

Table of Contents:

List of References:	p. 2
Table of Cited Authorities:	p. 3
Real Party in Interest:	p. 3
Related Appeals and Interferences:	p. 3
Status of Claims:	p. 4
Status of Amendments:	p. 4
Summary of Claimed Subject Matter:	p. 5
Grounds of Rejection to be Reviewed on Appeal:	p. 10
Argument:	p. 12
Claims Appendix:	p. 37
Evidence Appendix:	p. 57
Related Proceedings Appendix:	p. 58

List of References:

USPN 6,003,006 (Colella);
Gardner, J. Pharmaceutical scam: Use audit to detect 'Pyramid Cube Scheme', HFM,
September 1982, p. 72-74;
USPN 5,890,129 (Spurgeon)

Table of Cited Authorities:

Federal Courts Case Law:

Abbott Laboratories v. Portland Retail Druggists Association, 425 U.S. 1, 47 L.Ed. 2d 537 (U.S. 1976)
KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007).
Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 227 USPQ 657 (Fed. Cir. 1985)
Exxon Research and Engineering Co. v. U.S., 60 USPQ2d 1272 (Fed. Cir. 2001)
Fiers v. Revel, 25 USPQ2d 1601 (Fed. Cir. 1993)
Lighting World Inc. v. Birchwood Lighting Inc., 72 USPQ2d 1344 (Fed. Cir. 2004).
In re Mercier, 185 USPQ 774 (CCPA 1975)
Moore U.S.A. Inc. v. Standard Register Co., 56 USPQ2d 1225 (Fed. Cir. 2000)
In re Paulsen, 31 USPQ2d 1671 (Fed. Cir. 1994)
Pickholtz v. Rainbow Technologies Inc., 62 USPQ2d 1340 (Fed. Cir. 2002)
Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd., 83 USPQ2d 1169 (Fed. Cir. 2007)
Young v. Lumenis Inc., 83 USPQ2d 1191 (Fed. Cir. 2007)
British Telecommunications PLC v. Prodigy Communications Corp., 62 USPQ2d 1879 (S.D.N.Y. 2002),

BPAI Case Law:

Ex Parte Keung, 17 USPQ2d 1545, 1547 (B.P.A.I. 1989)
Ex Parte Maizel, 27 USPQ2d 1662, 1665 (B.P.A.I. 1992)

Manual of Patent Examining Procedure:

Sections 2141.03, 2173.02, and 2173.05(b)

i. Real Party in Interest:

The real party in interest is Health Resources, USA, L.L.C., which is the assignee of the subject application.

ii. Related Appeals and Interferences:

None

iii. Status of Claims:

As set forth in the table below, (1) claims 1-23, 25, 27-30, 32-49, 62-66, and 68-80 (which represent all of the currently pending claims) stand rejected, and (2) claims 24, 26, 31, 50-61, and 67 stand canceled from the application.

<u>Claim</u>	<u>Status</u>	<u>Claim</u>	<u>Status</u>	<u>Claim</u>	<u>Status</u>	<u>Claim</u>	<u>Status</u>
1	Rejected	21	Rejected	41	Rejected	61	Canceled
2	Rejected	22	Rejected	42	Rejected	62	Rejected
3	Rejected	23	Rejected	43	Rejected	63	Rejected
4	Rejected	24	Canceled	44	Rejected	64	Rejected
5	Rejected	25	Rejected	45	Rejected	65	Rejected
6	Rejected	26	Canceled	46	Rejected	66	Rejected
7	Rejected	27	Rejected	47	Rejected	67	Canceled
8	Rejected	28	Rejected	48	Rejected	68	Rejected
9	Rejected	29	Rejected	49	Rejected	69	Rejected
10	Rejected	30	Rejected	50	Canceled	70	Rejected
11	Rejected	31	Canceled	51	Canceled	71	Rejected
12	Rejected	32	Rejected	52	Canceled	72	Rejected
13	Rejected	33	Rejected	53	Canceled	73	Rejected
14	Rejected	34	Rejected	54	Canceled	74	Rejected
15	Rejected	35	Rejected	55	Canceled	75	Rejected
16	Rejected	36	Rejected	56	Canceled	76	Rejected
17	Rejected	37	Rejected	57	Canceled	77	Rejected
18	Rejected	38	Rejected	58	Canceled	78	Rejected
19	Rejected	39	Rejected	59	Canceled	79	Rejected
20	Rejected	40	Rejected	60	Canceled	80	Rejected

iv. Status of Amendments:

No amendment has been filed subsequent to the Final Office Action.

v. Summary of Claimed Subject Matter:

Independent claims 1 and 62 (as well as all of the claims dependent therefrom) address a method whereby retail pharmacies can be provided with "own use" discounts for certain ones of their pharmaceutical purchases. As described in the subject patent application, the inventor believes that retail pharmacies have been unable to obtain "own use" discounted pharmaceuticals because pharmaceutical sellers fear that retail pharmacies will "divert" the "own-use"-discounted pharmaceuticals to end users who are not "own use" discount eligible. (See Patent Application; p. 2, lines 12-17; p. 4, lines 14-21). The inventor believes that this inability to purchase "own use"-discounted pharmaceuticals is experienced by retail pharmacies even when those retail pharmacies are purchasing pharmaceuticals on behalf of "own-use" eligible institutions such as nursing homes. (See Patent Application; p. 3, lines 30-32). This is a great problem for the nursing home industry, where an estimated 45% of nursing homes purchase their pharmaceuticals from retail pharmacies, thereby unnecessarily contributing to this nation's crippling health care costs. (See Patent Application; p. 3, line 30- p. 4, line 2; p. 4, lines 14-21).

For a better understanding of this problem, a background discussion of the "own use" discount and the issue of "diversion" is in order. As stated in the patent application:

The Robinson-Patman Price Discrimination Act, 15 USC §13(a), generally makes it unlawful for one engaged in commerce to discriminate in price between different purchasers of like commodities where, among other things, "the effect of such discrimination may be substantially to lessen competition." Abbott Laboratories v. Portland Retail Druggists Association, 425 U.S. 1, 3-4, 47 L.Ed. 2d 537, 543 (1976). This United States law essentially prevents pharmaceutical sellers from selling a given type of pharmaceutical at regular price to one buyer and then selling that same type of pharmaceutical at a discounted price to another buyer. However, an exception to the Robinson-Patman Act exists stating that "nothing in the [Robinson-Patman Act], shall apply to purchases of their supplies for their **own use** by schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit." 15 USC §13c. Because of this exception, hospitals, nursing homes, long term health care facilities, and the like are eligible for purchasing pharmaceuticals at a discounted price -- an "own use" discount -- when they are buying pharmaceuticals on behalf of their patients or in some situations, their employees. Therefore, when nursing homes purchase pharmaceuticals on behalf of their patients, they are eligible to purchase such pharmaceuticals from the pharmaceutical manufacturer at a discounted price. (See Patent Application; p. 1, line 2 – p. 2, line 7).

However, merely because nursing homes are legally entitled to receive "own use" discounts does not mean that they will in fact receive those discounts in the real world. In the real world, most nursing homes purchase their pharmaceuticals from middle men. (See Patent Application; p. 2, lines 8-12). Because these middle men also purchase pharmaceuticals on behalf of buyers that are not "own use" eligible, pharmaceutical sellers are highly reluctant to sell "own use"-discounted pharmaceuticals to such middle men for fear of "diversion" by the middle men. (See Patent Application; p. 2, lines 12-17).

As an example of "diversion", assume middle man X buys 10,000 units of Pharmaceutical Y from Pharmaceutical Seller Z at an "own use"-discounted price of \$1/unit, wherein the normal non-discounted price to middle men is \$2/unit, and wherein the normal sales price to a retail seller is \$2.25/unit. In an exemplary diversion scenario, Middle Man X sells the 10,000 units to a buyer who is not "own use" eligible at a price of \$1.75/unit, for a profit of \$7,500. In doing so, Middle Man X has defrauded Pharmaceutical Seller Z of \$10,000 and has trebled their profits, which would have been \$2,500 had Pharmaceutical Seller Z known that Middle Man X was selling the pharmaceuticals to a buyer not eligible for the "own use" discount.

Against this backdrop, and as stated above, the inventor notes that a large percentage of nursing homes, which are "own use" eligible institutions, are unable to purchase pharmaceuticals at an "own use"-discounted price because they purchase their pharmaceuticals through retail pharmacies. Because retail pharmacies supply large amounts of pharmaceuticals to walk-in customers who are not "own use"-eligible, the inventor believes that pharmaceutical sellers are unwilling to sell "own use"-discounted pharmaceuticals to retail pharmacies even when the retail pharmacy is supplying those pharmaceuticals to a nursing home. (See Patent Application; p. 3, line 20 – p. 4, line 2). These retail pharmacies can be contrasted with "closed pharmacies" which are generally given "own use" discounts by pharmaceutical sellers.

A closed pharmacy is a pharmacy that supplies pharmaceuticals to institutions such as hospitals or nursing homes, but does not sell pharmaceuticals to walk-in customers. Because these closed pharmacies have an exclusive customer list of customers who are eligible to buy pharmaceuticals at an "own use" discount, pharmaceutical manufacturers are willing to sell pharmaceuticals to these closed pharmacies at a discounted price. That is, pharmaceutical manufacturers are not

overly worried that the "closed pharmacy" will sell discounted pharmaceuticals at a regular price to customers ineligible for a discount, because the "closed pharmacy" has virtually no such customers. (See Patent Application; p. 3, lines 11-19).

In an effort solve this problem, claim 1 recites a method whereby orders from certain buyers are audited to determine whether the order is entitled to an "own use" discount. By following the auditing method recited in claim 1, the buyer can verify to a seller's satisfaction that the pharmaceuticals being ordered are in fact destined for "own use" eligible customers. Claim 1 recites the step of receiving a pharmaceutical order from a buyer, wherein "said buyer comprises one from a group consisting of (1) ***an entity comprising at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home***, and (2) ***at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home...***" (See Patent Application; e.g., p. 6, lines 3-8; Figures 5-6 (emphasis added)).

Claim 1 further recites the step of "receiving an associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer". This report comprises data that evidences the buyer's eligibility for an "own use" discount. (See Patent Application; p. 10, line 1 – p. 13, line 23; Figures 2(a)-4).

Upon receipt of the report, claim 1 recites the step of "comparing said order with said associated report to determine whether said associated report supports said order". (See Patent Application; p. 17, line 1- p. 20, line 10; Figure 9 (steps 446-450)).

Lastly, claim 1 recites the step of "responsive to said comparison, making a status determination as to whether said buyer qualifies for purchasing said quantity of said type of pharmaceutical at a price reduced by an 'own use' discount." While a one-to-one correspondence between the order quantity and the quantity documented by the report would result in a determination that the report supports the order, the inventor further notes that a tolerance can optionally be incorporated into this status determination. (See Patent Application; p. 7, lines 28-31; p. 17, lines 8-27; p. 19, lines 2-5; Figure 9 (step 452)).

Through these steps, claim 1 recites a new, useful and nonobvious method by which a reliable determination can be made that pharmaceuticals purchased by retail pharmacies with nursing home customers are entitled to an "own use" discount.

Claim 62 recites a method similar to claim 1, wherein claim 62 recites a step of determining an "own use" discount status for a "proposed 'own use' purchase by a buyer", wherein the buyer "comprises at least one selected from the group consisting of (1) a **retail pharmacy** that supplies pharmaceuticals to at least one hospital, nursing home, or long term health care facility where said at least one patient resides, and (2) **an entity comprising a plurality of said retail pharmacies**" (emphasis added). Claim 62 further recites that this "own use" discount status determination is made "on the basis of a comparison between the proposed purchase and information that summarizes at least one "own use" pharmaceutical need of at least one patient who is supplied with the pharmaceutical by the buyer".

Independent claim 30 addresses an auditing system for making such an "own use" status determination for pharmaceutical orders from a buyer. Claim 30 recites that software executed by a processor within the system be configured to "confirm whether said buyer is any of a group consisting of (a) **an entity comprised of at least one retail pharmacy** that supplies pharmaceuticals to at least one nursing home, and (b) **at least one retail pharmacy** that supplies pharmaceuticals to at least one nursing home..." (emphasis added).

Independent claims 16 and 69 recite a method and system respectively, wherein two forms of documentation are needed to audit an order to establish the order's entitlement to an "own use" discount. (See Patent Application, e.g., p. 16, lines 15-17; p. 13, lines 18-23). Independent method claim 16 recites the steps of:

- receiving **a first associated report** summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer;
- receiving **a second associated report** summarizing the "own use" pharmaceutical needs of said at least one patient who is supplied with pharmaceuticals by said buyer;
- analyzing **said first associated report and said second associated report to determine an extent to which they support said order**; ... (emphasis added).

Claim 69 similarly recites that a computer be configured to base its "own use" audit "on at least two types of audit data that are compared to said order." (See Patent Application; Figure 7 (computer 300)).

As examples, the specification identifies a preferred embodiment wherein a retail pharmacy listing and a physician's order sheet (POS) from a nursing home are used as these

first and second associated reports (and two forms of audit data). (See Patent Application; p. 13, lines 18-23).

By basing its audit on two reports/two forms of audit data, the invention of claims 16 and 69 improves the reliability of the audit. (See Patent Application, e.g., p. 16, lines 15-17).

Independent claim 76 recites a method that includes the following steps:

- receiving an order comprising a request from a buyer for a quantity of a type of pharmaceutical;
- receiving an associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer;
- comparing said order with said associated report to determine whether said associated report supports said order;
- responsive to said comparison, making a status determination as to whether said buyer qualifies for purchasing said quantity of said type of pharmaceutical at a price reduced by an "own use" discount; and
- responsive to said comparison resulting in a status determination that said buyer does not qualify for said discount, adjusting said order so that said order is supported by said associated report.

Thus, claim 76 further recites that orders can be adjusted so that they are supported by the report that evidences the buyer's entitlement to an "own use" discount. This aspect of claim 76 is disclosed in the specification at p. 6, lines 20-23, p. 7, line 31 – p. 8, line 2, and Figure 9 (steps 454-456)). By adjusting orders in response to the audit comparison, the method of claim 76 allows buyers to maximize their entitlement to "own use" discounts even if the order is somewhat inaccurate with respect to its "own use" entitlement and/or the order pools orders for "own use" eligible and "own use" ineligible customers. Independent claim 75 recites a computer that is configured to perform such order adjustments.

vi. Grounds of Rejection to be Reviewed on Appeal:

I. Whether claim 69 is unpatentable under 35 U.S.C. 112, first paragraph as being based on a nonenabling disclosure.

II. Whether claims 37, 43-44, and 69-74 are unpatentable under 35 U.S.C. 112, second paragraph as being indefinite; and more specifically:

(a) whether claims 37 and 43-44 are indefinite; and

(b) whether claims 69-74 are indefinite

III. Whether claims 1, 9-10, 12-13, 15-23, 25, 27-30, 32-37, 45-49, 62-66, and 68-80 are unpatentable under 35 U.S.C. 103 over Colella (USPN 6,003,006) in view of Gardner ("Pharmaceutical Scam: Use Audit to Detect 'Pyramid Cube Scheme'"); and more specifically:

(a) whether claim 1 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(b) whether claim 62 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(c) whether claim 65 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(d) whether claim 66 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(e) whether claim 30 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(f) whether claim 76 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(g) whether claim 75 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(h) whether claims 28, 48, 68, and 73 (including any and all claims dependent therefrom) are obvious in view of Colella and Gardner;

(i) whether claims 29, 49, and 77 (including any and all claims dependent therefrom) are obvious in view of Colella and Gardner;

(j) whether claim 16 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(k) whether claim 17 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(l) whether claim 69 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner;

(m) whether claims 70 and 79 (including any and all claims dependent therefrom) are obvious in view of Colella and Gardner; and

(n) whether claim 64 (including any and all claims dependent therefrom) is obvious in view of Colella and Gardner.

IV. Whether claims 2-8, 11, 14, and 38-44 are unpatentable under 35 U.S.C. 103 over Colella in view of Gardner and further in view of Spurgeon (USPN 5,890,129).

vii. Argument:

Applicant will now address the various rejections made in the Final Office Action and explain why these rejections must be reversed on appeal.

I. Claim 69 does not violate 35 USC 112, first paragraph because claim 69 is not a single element “means plus function” claim; the recited “computer configured to ...” limitation in claim 69 does not invoke 35 USC 112, paragraph 6 because the term “computer” connotes sufficient structure to avoid classification as a “means plus function” limitation.

The Final Office Action rejected claim 69 under 35 U.S.C. 112, first paragraph “because the specification does not reasonably provide enablement for a claim covering every conceivable means for achieving the recited purpose”. (See Final Office Action; p. 2). Claim 69 reads as follows:

69. A system for determining whether a pharmaceutical buyer qualifies for an “own use” discount, said system comprising:
a computer configured to perform an “own use” audit on a pharmaceutical order to determine whether said order qualifies for an “own use” discount, said audit being based on at least two types of audit data that are compared to said order.

This rejection of claim 69 is premised on the Examiner’s interpretation of the “computer” limitation of claim 69 as being a “means plus function” limitation. (See Final Office Action; p. 2). Under such an interpretation, the Examiner asserts that claim 69 is a single element “means plus function” claim in violation of 35 U.S.C., first paragraph.

However, Applicant respectfully submits that it is improper to interpret the “computer” limitation of claim 69 as a “means plus function” limitation. Applicant notes that claim 69 fails to recite the term “means”, thereby triggering a strong presumption that the “computer” limitation of claim 69 is not a “means plus function” limitation.

[A] claim term that does not use ‘means’ will trigger the rebuttable presumption that § 112 ¶ 6 does not apply. [citation omitted] ... The presumption that a limitation lacking the term “means” is not subject to section 112 ¶ 6 can be overcome if it is demonstrated that “the claim term fails to ‘recite sufficiently definite structure’ or else recites ‘function without reciting sufficient structure for performing that function’”. [citations omitted] Our cases make clear, however, that the presumption flowing from the absence of the term “means” is

a strong one that is not readily overcome. [citations omitted] Lighting World Inc. v. Birchwood Lighting Inc., 72 USPQ2d 1344, 1348 (Fed. Cir. 2004).

Within this framework, Applicant respectfully submits that the limitation “a computer configured to perform an ‘own use’ audit...” in claim 69 recites a sufficiently definite structure that can perform the “own use” audit – namely the structure of a “computer”. Applicant further submits that the Final Office Action’s reliance on Fiers v. Revel, 25 USPQ2d 1601 (Fed. Cir. 1993), Ex Parte Maizel, 27 USPQ2d 1662, 1665 (B.P.A.I. 1992), and Ex Parte Keung, 17 USPQ2d 1545, 1547 (B.P.A.I. 1989) is misplaced as these cases pertain to biotechnology claims in an unpredictable art as opposed to a claim in the computer arts. As recognized in British Telecommunications PLC v. Prodigy Communications Corp., 62 USPQ2d 1879, 1883-84 (S.D.N.Y. 2002), the term “computer” in a claim limitation represents sufficient structure to prevent the claim limitation from being treated as a “means plus function” limitation.

[T]he “central computer means” is not a means-plus-function claim. The functions of the central computer are stated in the claim language, however, the claim recites the entire structure necessary to perform the claimed function. [citation omitted] ***That structure is a computer.*** British Telecommunications, 62 USPQ2d at 1884 (emphasis added).

The court in British Telecommunications reached this conclusion even though the claim limitation at issue used the term “means”, thereby triggering the presumption that the “central computer means” was a “means plus function” limitation. Id. at 1883. Thus, with claim 69 the conclusion that the “computer” limitation is not a “means plus function” limitation is further enhanced given that claim 69 operates in an environment that already begins with a strong presumption against treatment as a “means plus function” limitation.

Applicant further notes that the specification describes computers in accordance with their conventional meaning in the art. For example, the specification, with reference to Figure 7, describes an embodiment where a computer 300 is employed to perform “own use” audits. (See Patent Application; p. 20, line 19 et seq.; Figure 7). Moreover, Figure 9 illustrates a flowchart for software that can be deployed on computer 300 to perform an “own use” audit. (See Patent Application; p. 24, line 21 et seq.; Figure 9). Applicant thus uses the term “computer” in claim 69 in accordance with its conventional meaning. The fact that persons having ordinary skill in the art would understand the meaning of a “computer” is further

reinforced by the Federal Circuit decisions In re Paulsen, 31 USPQ2d 1671, 1673-74 (Fed. Cir. 1994) (interpreting the claim term "computer" in a claim without even raising the issue of classifying the term "computer" as a "means plus function" limitation) and Pickholtz v. Rainbow Technologies Inc., 62 USPQ2d 1340, 1344-45 (Fed. Cir. 2002) (also interpreting the claim term "computer" in a claim without even raising the issue of classifying the term "computer" as a "means plus function" limitation).

Accordingly, for the foregoing reasons, Applicant respectfully submits that it was error for the Examiner to interpret the "computer" limitation in claim 69 as a "means plus function" limitation, thereby rendering it an error to reject claim 69 as a single element "means plus function" claim. Reversal of this rejection is respectfully requested.

II. The term "sufficient" in claims 37, 43 and 44 does not render those claims indefinite.

The Final Office Action rejected claims 37 under 35 U.S.C. 112, second paragraph "because the term 'sufficient' in claim 37 is a relative term, which renders the claim indefinite". (See Final Office Action; p. 3-4). Claims 43-44 were rejected under the same rationale. The Final Office Action further stated "[t]he term 'sufficient' is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention." (See Final Office Action; p. 4).

Claim 37 reads as follows:

37. The pharmaceutical order auditing system of claim 35 wherein said order data further comprises a plurality of identifiers for each of said patients needing said quantity of said type of pharmaceutical, wherein said audit data further comprises a plurality of identifiers for each of said patients in each of said nursing homes needing each of said amounts of said type of pharmaceuticals, and wherein said software is further configured to compare said patient identifiers in said audit data with said patient identifiers in said order data, said status determination further depending upon ***whether said patient identifier comparison results in a sufficient number of matches between said audit data patient identifiers and said order data patient identifiers.*** (emphasis added).

Claims 43 and 44 include similar limitations.

"Claims are considered indefinite when they are 'not amenable to construction or are insolubly ambiguous Thus, the definiteness of claim terms depends on whether those terms can be given any reasonable meaning.'" Young v. Lumenis Inc., 83 USPQ2d 1191, 1197 (Fed. Cir. 2007) (finding that the claim term "...incision in the epidermis *near* the edge of the ungual crest..." is not indefinite). In assessing whether a claim term is indefinite, consideration of intrinsic evidence such as the specification is appropriate. Young, 83 USPQ2d at 1197.

Similarly, as recognized in Section 2173.05(b) of the Manual of Patent Examining Procedure (MPEP):

When a term of degree is presented in a claim, ***first a determination is to be made as to whether the specification provides some standard for measuring that degree.*** If it does not, a determination is made as to whether one of ordinary skill in the art, in view of the prior art and the status of the art, would be nevertheless reasonably apprised of the scope of the invention. (See MPEP §2173.05(b) (emphasis added)).

In the indefiniteness rejection of claim 37, the Final Office Action summarily concludes that "the specification does not provide a standard for ascertaining" the meaning of "sufficient" in claim 37. However, Applicant respectfully disagrees. At page 23, lines 7-19, the specification describes what is meant by "a sufficient number of matches" in the context of a "patient identifier comparison".

Next, the software can compare the patients identified in the order data with the patients identified in the audit data to verify that there is a patient match between the order data and the audit data. ***As previously discussed, the patient data also need not be an exact one-to-one match***, although it would be preferable. ***In such cases, the software can attribute a percentage patient match to the comparison.***

If the software determines that there is a type match, a sufficient size match, and a ***sufficient patient match***, the software can produce a status report indicating that a status determination has been made verifying that the buyer does in fact qualify for purchasing the quantity of pharmaceuticals in the order at a price reduced by an "own use" discount. Of course, if the software determines that there is not a type match, a sufficient size match, or a sufficient patient match, the status report can indicate that a status determination has been made that the buyer does not qualify for the discount based on the original order. (See Patent Application; p. 23, lines 7-19 (emphasis added)).

Thus, the specification provides a clear standard for interpreting the term “sufficient number of matches” in claim 37. As explained in the specification, the term “sufficient number of matches” describes a number of patient identifier matches that are within a defined percentage of all patient identifier matches, thereby providing a tolerance to the patient identifier comparison. The specification further discloses a preferable “sufficiency parameter” for use by the auditing software of Figure 9 having a value of 90% for patient matches. (See Patent Application; p, 24, lines 31-32).

Based on this clear guidance in the specification as to how “sufficient” should be interpreted in claims 37 and 43-44, Applicant respectfully submits that it was error for the Examiner to reject claim 37 and claims 43-44 for indefiniteness. See Young, 83 USPQ2d at 1198 (“When intrinsic evidence resolves the claim construction, a term is not ‘insolubly ambiguous,’ and thus reference to the prior art is not needed.”). As stated in Section 2173.02 of the MPEP:

The examiner’s focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. ... Some latitude in the manner of expression and the aptness of terms should be permitted even through the claim language is not as precise as the examiner might desire. (See MPEP §2173.02).

Therefore, Applicant respectfully submits that claims 37 and 43-44 comply with 35 USC Section 112, second paragraph. (See also Exxon Research and Engineering Co. v. U.S., 60 USPQ2d 1272 (Fed. Cir. 2001) (holding that the term “sufficient” in a claim did not render the claim indefinite) and Moore U.S.A. Inc. v. Standard Register Co., 56 USPQ2d 1225 (Fed. Cir. 2000) (providing an interpretation for the claim term “distance sufficient” without finding the claim indefinite)).

III. The separately recited terms “computer” and “second computer” in claims 69-74 do not render those claims indefinite.

The Final Office Action rejected claims 69-74 for indefiniteness because these claims recite both “a computer” and “a second computer”. (See Final Office Action; p. 4). Claims 69

and 70 (as well as intervening claim 74) read as follows (with the pertinent claim limitations highlighted):

69. A system for determining whether a pharmaceutical buyer qualifies for an "own use" discount, said system comprising:
a computer configured to perform an "own use" audit on a pharmaceutical order to determine whether said order qualifies for an "own use" discount, said audit being based on at least two types of audit data that are compared to said order.

74. The system of claim 69 wherein said at least two types of audit data comprise:
a retail pharmacy listing that summarizes the pharmaceutical needs of a nursing home to which that retail pharmacy supplies pharmaceuticals; and
data from the nursing home that summarizes a pharmaceutical need of at least one patient of that nursing home.

70. The system of claim 74 further comprising:
a second computer in communication with **said computer** via a network, **said second computer** being configured to provide **said computer** with said retail pharmacy listing, and wherein **the computer** is further configured to perform said "own use" audit by comparing said order with said said retail pharmacy listing.

Applicant notes that claim 70 adds a "second computer" to the system of claim 69. As an initial matter, Applicant notes that the Examiner's indefiniteness rejection of claims 69-74 is entirely inapplicable to claims 69 and 73 because these claims do not recite the "second computer" limitation that the Examiner contends is the source of the indefiniteness. As such, Applicant notes that the indefiniteness rejection of claims 69 and 73 must be reversed for this reason.

Furthermore, while the "computer" recited in claim 69 is configured to "perform an 'own use' audit", the "second computer" added in claim 70 is configured to "provide said computer with said retail pharmacy listing". As such, Applicant respectfully submits that claims 69 and 70 are clear in their recitations of a "computer", a "second computer" and their respective functional operations within the system. With respect to the Examiner's statement that these claims are unclear as to "how many computers are present", Applicant notes that claim 70 clearly recites the presence of two computers. Furthermore, with respect to the Examiner's statement that it is unclear as to which of these computers the term "said

computer" refers, Applicant notes that claim 70 clearly uses the phrase "said second computer" to refer to the "second computer" added by claim 70 while using the phrase "said computer" to refer to the "computer" recited in claim 69. These formulations are made using standard antecedent basis terms common to claims. Therefore, Applicant respectfully submits that the indefiniteness rejections of claims 69-74 is in error and must be reversed.

IV. The Colella and Gardner references fail to render independent method claim 1 obvious because those references fail to render obvious the concept of performing an audit on a pharmaceutical order from a buyer to determine whether the order qualifies for an "own use" discount, wherein the buyer comprises a member of the "group consisting of (1) an entity comprising at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (2) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home".

The Final Office Action rejected independent method claim 1 for obviousness based on the combination of the Colella and Gardner references. The Final Office Action asserted that Colella discloses all aspects of claim 1 with the exception of the step of "making a status determination". (See Final Office Action; pages 5-6). Nevertheless, the Final Office Action found that "Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts", and the Final Office Action further concluded that it would have been obvious to modify Colella's method/system to check/verify whether pharmaceutical purchases qualify for "own use" discounts for the purpose of avoiding legal violations while still enjoying cost containment benefits, as taught by Gardner. (See Final Office Action; p. 6, citing Gardner at page 74, paragraph 4).

However, Applicant respectfully submits that this obviousness rejection is in error. First, the Final Office Action based its rejection on mistaken interpretations of the Colella and Gardner references, both individually and in combination. For example, Applicant respectfully submits that contrary to the assertion on page 5 in the Final Office Action, Colella fails to disclose a step of receiving an order from a buyer, wherein the buyer comprises "an entity comprised of at least one retail pharmacy". Furthermore, Gardner expressly discourages hospitals from selling excess pharmaceuticals to "questionable brokers/business enterprises" who supply "small drugstores" (e.g., retail pharmacies). (See Gardner; p. 74). Gardner

discloses no techniques that can be used to establish that the “questionable brokers/business enterprises” are entitled to an “own use” discount. Instead, Gardner discloses that hospitals should perform audits on their own inventory to ensure that such brokers are not purchasing the hospital’s excess pharmaceutical stock. (See Gardner; p. 74, the paragraphs following the “Audit checks to consider”).

Second, the Final Office Action based its rejection on a mistaken interpretation of claim 1. Following Applicant’s response dated March 14, 2006 to the first Office Action, the Examiner recognized Applicant’s arguments that Colella fails to address the issues faced by retail pharmacies. (See Final Office Action; p. 37). However, the Examiner discounted these arguments based on a mistaken interpretation of claim 1 when the Final Office Action stated: “it is noted that the features upon which applicant relies (i.e., the involvement of retail pharmacies) are not recited in the rejected claim(s).” (See Final Office Action; p. 37). Contrary to the Examiner’s mistaken assertion, claim 1 does in fact require that the buyer be either “***an entity comprising at least one retail pharmacy*** that supplies pharmaceuticals to at least one nursing home” or “***at least one retail pharmacy*** that supplies pharmaceuticals to at least one nursing home”. These and other errors will be explained in greater detail below.

The Supreme Court recently reinforced that the *Graham* factors still lay the framework for addressing the question of whether a claimed invention is obvious. KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1391 (U.S. 2007). These factors are:

- 1) “the scope and content of the prior art”;
 - 2) the “differences between the prior art and the claims”;
 - 3) “the level of ordinary skill in the pertinent art”; and
 - 4) objective evidence of nonobviousness.
- Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd., 83 USPQ2d 1169, 1174 (Fed. Cir. 2007) (quoting *KSR*).

(1) The Scope and Content of the Prior Art

Colella discloses a method/system that provides inventory tracking and drug distribution functionality for “health care providers such as hospitals”. (See Colella, col. 1, lines 6-16). The basic actors in the Colella system are hospital staff who dispense drugs to patients, the hospital pharmacy which manages the hospital’s drug inventory, and a drug distributor which supplies the hospitals’ drug needs. Toward this end, Figure 1A of Colella

discloses a system wherein patients' drug needs are entered by nurses through "drug distribution machines" (DDMs) 18 located at nursing stations 16. (See Colella; col. 4, lines 1-7; Figure 1A). The DDMs forward this drug consumption information to the hospital's "central pharmacy computer" (CPC) 20, wherein the CPC runs a Drug Inventory Management Software (DIMS) program to manage the hospital's drug inventory needs. (See Colella; col. 4, lines 7-9; Figure 1A). The CPC can then communicate with a "drug distribution center computer" (DCC) that also runs a DCC counterpart to the DIMS program, wherein the DIMS programs executed by the CPC and DCC can work with each other to automatically supply the hospitals' drug needs based on information collated from the various DDMs 18. (See Colella; col. 4, lines 10-53).

Gardner warns hospitals that the sale of excess drug inventory to "questionable brokers/business enterprises" who supply "small drugstores" may violate a variety of laws. (See Gardner; page 74; Exhibit 1). Gardner describes a "pyramid cube scheme" where such brokers approach "hospital purchasing personnel" in an effort "to convince them [the hospital purchasing personnel] to over-order pharmaceuticals for the purpose of reselling the excess pharmaceuticals to them [the brokers] for a profit, thereby reducing the hospital's costs." (See Gardner; p. 74). Gardner further warns that "[t]he pharmaceutical products selected by the brokers are normally only sold direct or via authorized dealerships to the hospital intended for its own use and not for resale purposes." (See Gardner, p. 74).

The excess pharmaceuticals, warehoused in the hospital, are then resold and delivered by the brokers to local satellite clinics and small drugstores at a profit to the hospital and the brokers. Although a profit margin is incorporated in the price, the small institutions/businesses are now able to purchase the goods at a lower cost than they would normally pay to the manufacturer or dealerships. The greater the volume ordered by the hospital, the lower the obtainable bid price – the greater the margin for profit. (See Gardner; p. 74).

Gardner notes that such practices raise a number of legal concerns. (see Gardner; p. 74; section entitled "Legal aspects and ramifications").

As a solution to this problem, Gardner advises hospitals to conduct audits for the purpose of identifying whether such "pyramid cube scheme" diversion to "questionable brokers" is occurring. (See Gardner; p. 74 ("This article is intended to encourage hospitals to

double check their internal procedures to ascertain if this practice is occurring. It can be checking using the audit process.”). Gardner describes auditing measures that can be used to illuminate whether a hospital is engaging in a “pyramid cube scheme” for diversion in the section entitled “Audit checks to consider”. (See Gardner; p. 74). Lastly, Gardner concludes with the teaching:

A shared purchasing agreement, used legally to obtain preferential prices for goods for one’s “own use,” is an acceptable approach to cost containment. The “Pyramid Cube Scheme,” used as an illegal profit for others, should be discouraged, especially for all tax-exempt hospitals. (See Gardner; p. 74).

Thus, Gardner provides strong teachings that hospitals should not sell pharmaceuticals from their inventory to brokers who supply small drugstores by characterizing such a practice as an illegal pyramid cube scheme.

(2) The Differences Between the Prior Art and Claim 1

Colella fails to disclose an auditing process that compares a pharmaceutical order from a buyer with an associated report to assess whether the order is entitled to an “own use” discount. It is important to note that Colella addresses an inventory tracking/ordering system for hospitals’ *in-house pharmacies*.

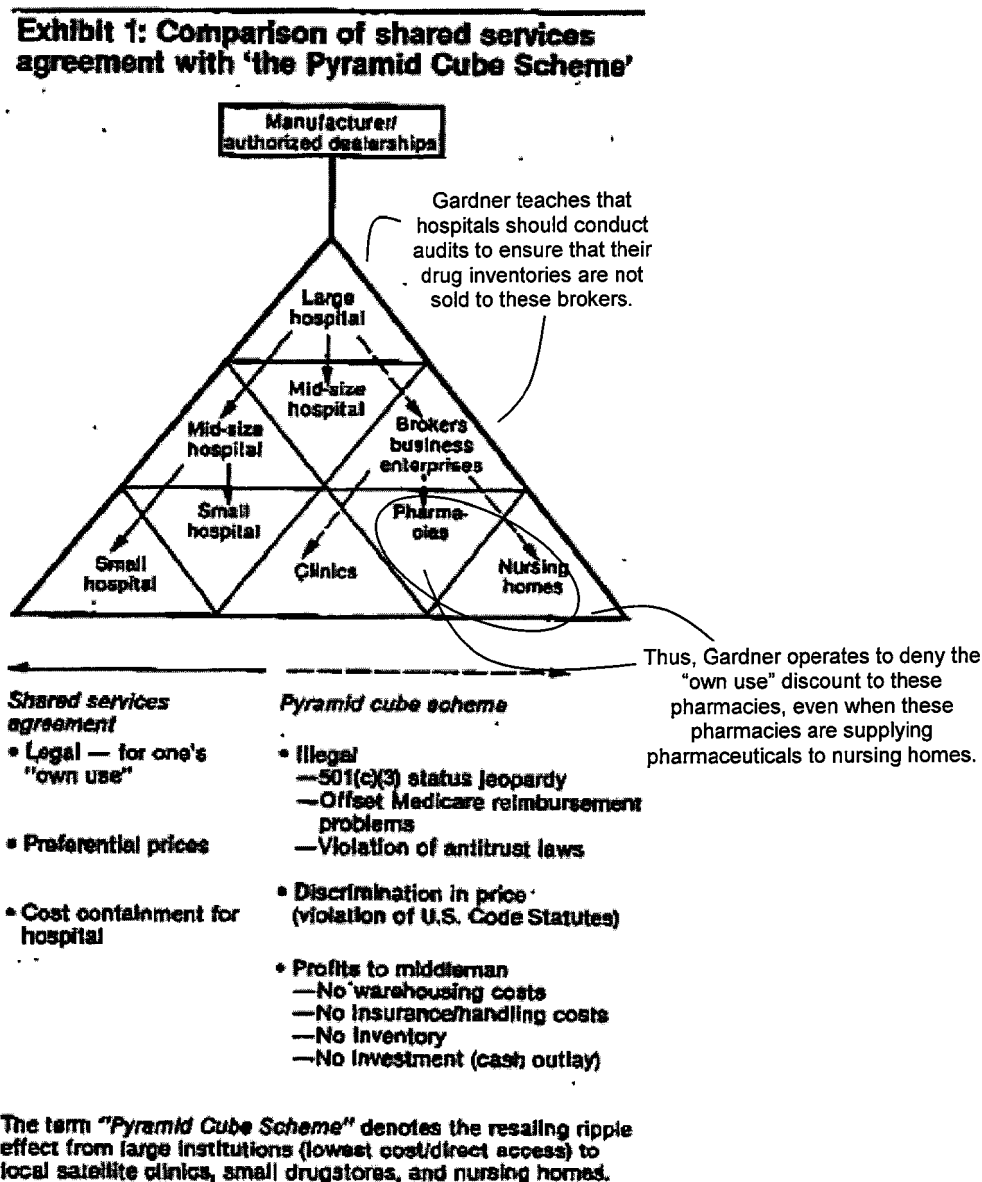
It has been known for health care providers, such as hospitals, to have *a pharmacist or pharmacy department within the hospital* to coordinate the dispensing of drugs to the patients of the health care institution. The pharmacists in such health care institutions have long been burdened with the increasingly complex record keeping and inventory management that results from hospitals caring for hundreds, if not thousands of patients every day. (See Colella; col. 1, lines 13-20 (emphasis added)).

Such in-house pharmacies fall into the class of “closed pharmacies” discussed in the patent application at page 3, lines 11-19 and in Section v above. With a closed pharmacy such as a hospital’s in-house pharmacy, sellers are willing to sell “own use”-discounted pharmaceuticals thereto because those closed pharmacies do have a retail customer base to which the “own use”-discounted pharmaceuticals can be readily diverted. As explained above and in the patent application, sellers such as the “drug distributor” of Colella have been historically unwilling to

sell “own use”-discounted pharmaceuticals to retail pharmacies (as opposed to closed pharmacies) for fear of diversion. The method of claim 1 is expressly limited to an auditing process that enables “one from a group consisting of (1) ***an entity comprising at least one retail pharmacy*** that supplies pharmaceuticals to at least one nursing home, and (2) ***at least one retail pharmacy*** that supplies pharmaceuticals to at least one nursing home” to purchase “own use”-discounted pharmaceuticals. Thus, even though the Final Office Action asserted that Colella addresses processing orders from a buyer wherein the buyer “includes an entity comprised of at least one retail pharmacy...” (see Final Office Action; p. 5), Applicant respectfully submits that Colella addresses only orders by hospitals’ in-house pharmacies who are already presumed entitled to the “own use” discount. The passages cited in the Final Office Action as disclosing the claim limitations relating to the retail pharmacy buyer of claim 1 (Colella at Figures 4 and 6; col. 5, lines 33-43) simply fail to address retail pharmacies in any way.

The Gardner reference also fails to disclose the concept of auditing pharmaceutical orders from buyers, wherein the buyer comprises “one from a group consisting of (1) an entity comprising at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (2) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home”. Gardner addresses tracking pharmaceutical usage within a hospital that has already presumably received an “own-use” discount. Gardner is silent with respect to a process for determining whether an order of pharmaceuticals on behalf of a nursing home but placed by a retail pharmacy (or an entity comprising at least one retail pharmacy) should be deemed eligible for an “own use” discount. Gardner teaches that hospitals should turn away and refuse to sell excess inventory to brokers who supply pharmaceuticals to “small drugstores”. (See Gardner; p. 74). To ensure that such brokers are refused business, Gardner teaches that hospitals should audit their own pharmaceutical usage, presumably to uncover whether any sales to brokers are occurring. (See Gardner; p. 74). Thus, while Gardner recognizes the existence of retail pharmacies (namely, the “small drugstores” which are supplied by the “questionable brokers”), Gardner addresses an auditing process for use by a hospital to prevent “own use”-discounted pharmaceuticals from reaching retail pharmacies rather than an auditing process that brings the “own use” discount to certain orders by retail pharmacies.

The Pyramid Cube Scheme exhibit (reproduced below) shown in Gardner serves as a case in point for the shortcomings of the Gardner reference relative to claim 1.



In contrast to the teachings of Gardner, the method of claim 1 addresses a technique for auditing orders from certain buyers to thereby establish those buyer's entitlement to an "own use" discount. In claim 1, the buyer can be a retail pharmacy that supplies pharmaceuticals to

a nursing home, whereas Gardner teaches an auditing process designed to prevent "own use" discounted pharmaceuticals from reaching such retail pharmacies. In claim 1, the buyer can also be an entity that comprises at least retail pharmacy, the at least one retail pharmacy supplying pharmaceuticals to a nursing home (such as a buyer's co-op), which would fall into the forbidden "broker" category in Gardner's "Pyramid Cube Scheme" exhibit.

Furthermore, when considered in combination with each other, the Colella and Gardner references fail to render claim 1 obvious. In combination, Colella's inventory tracking system merely serves as a useful tool for completing some of the "audit checks" listed by Gardner. However, these audits are still being performed, as per Gardner, to prevent the hospital from re-selling its excess inventory while Colella's system functions to automatically regulate the hospital's inventory so that it closely matches hospital needs. This combination still would not yield the method of claim 1, which operates to bring the "own use" discount to an entirely new class of buyers.

There is simply no teaching, suggestion, or motivation evident in the record apart from the inventor's patent application for using an auditing process to establish that an order from a buyer is entitled to an "own use" discount, wherein the buyer is "one from a group consisting of (1) an entity comprising at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (2) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home".

While the Final Office Action indicates that the Examiner considered Applicant's previous arguments in this regard, the Final Office Action further indicates that the Examiner discounted these arguments based on a misinterpretation of claim 1. (See Final Office Action; p. 37). In the "Response to Arguments" section of the Final Office Action, the Examiner states:

(C) Applicant argues that Colella fails to address issues faced by retail pharmacies.

It is noted that Applicant cites pages from the specification to discuss these features. In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the involvement of retail pharmacies) ***are not recited in the rejected claim(s)***. (See Final Office Action; p. 37 (emphasis added)).

However, contrary to this erroneous statement by the Examiner, the method of claim 1 is ***expressly limited*** to only orders from a buyer, wherein the buyer is “one from a group consisting of (1) ***an entity comprising at least one retail pharmacy*** that supplies pharmaceuticals to at least one nursing home, and (2) ***at least one retail pharmacy*** that supplies pharmaceuticals to at least one nursing home” (emphasis added).

While Applicant recognizes that the KSR decision has stressed that a rigid application of the “teaching, suggestion, or motivation” (TSM) test to the question of obviousness is inappropriate, KSR nevertheless notes that the TSM test is a “helpful insight” into the question of obviousness. KSR, 82 USPQ2d at 1396; see also Takeda, 83 USPQ2d at 1174 (“the [KSR] Court indicated that there is ‘no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis.’ [citation omitted] As long as the test is not applied as a ‘rigid and mandatory formula, that test can provide ‘helpful insight’ to an obviousness inquiry.”).

Furthermore, when one examines the concerns in KSR with respect to a rigid application of the TSM test, Applicant respectfully submits that the nonobvious nature of claim 1 is further supported. For example, the Supreme Court in KSR stated that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” KSR, 82 USPQ2d at 1395. With respect to claim 1, however, the prior art fails to establish that a predictable result of combining Colella with Gardner will be the extension of the “own use” discount to a buyer that is “one from a group consisting of (1) an entity comprising at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (2) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home”. In fact, an objective review of these references yields no predictions at all with respect to retail pharmacies other than hospitals should audit their inventories to ensure that brokers for such retail pharmacies are not purchasing drugs from those inventories.

Furthermore, the Supreme Court in KSR cautioned against focusing only on the problems/motivations of the inventor/patentee. Id. at 1397. However, even considering the known motivations from Colella and Gardner, the method of claim 1 is not rendered obvious. The combination of Gardner with Colella based on the motivations and teachings found in Gardner and Colella fail to reproduce the claimed invention. The motivation of Gardner is to

prevent pharmaceuticals that have already received an "own use" discount from being sold by hospitals to brokers who supply small drugstores. The primary motivation of Colella is to closely monitor drug inventories. When combined with each other, Colella and Gardner would lead a person having ordinary skill in the art to employ Colella's inventory tracking system to monitor the hospital's drug inventory as part of Gardner's suggested audit to determine whether any drugs are being diverted to "questionable brokers". However, once again, this combination fails to render the inventive method of claim 1 obvious.

Lastly, the Supreme Court in KSR recognized the continued validity of the principle that a strong indicator of nonobviousness are teachings in the prior art that teach away from combining elements. Id. at 1395 (citing U.S. v. Adams, 148 USPQ 479 (U.S. 1966)). In the instant case, Applicant respectfully submits that Gardner teaches away from the invention of claim 1 because Gardner teaches the use of an audit process designed to prevent brokers who supply small drugstores from receiving "own use"-discounted pharmaceuticals, thereby preventing those small drugstores from receiving "own use"-discounted pharmaceuticals. As reflected in the Pyramid Cube Scheme of Exhibit 1 in Gardner, this carte blanche discouragement of discounted sales exists even in situations where those small drugstores are supplying the pharmaceuticals to nursing homes, which are themselves "own use" discount eligible. In direct contradiction to this teaching, claim 1 addresses a method employing an audit process that brings the "own use" discount to parties denied the "own use" discount by Gardner, namely a buyer that is "one from a group consisting of (1) an entity comprising at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (2) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home". Therefore, Applicant respectfully submits that teachings in Gardner that teach away from the invention of claim 1 further mandate that the Examiner's obviousness rejection of claim 1 must be reversed.

As is well-settled, "all of the relevant teachings of the cited references must be considered in determining what they fairly teach to one having ordinary skill in the art. [citations omitted] The relevant portions of a reference include not only those teachings which would suggest particular aspects of an invention to one having ordinary skill in the art, but also those teachings which would lead such a person away from the claimed invention." In re

Mercier, 185 USPQ 774, 778 (CCPA 1975) (emphasis in original) (*see also* Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 227 USPQ 657,667, 669, fn 33 (Fed. Cir. 1985) (finding error by the district court where the district court's obviousness analysis used the claims as blueprint and failed to give "due consideration for teachings in [the prior art] references that would have led one skilled in the art to find it improper to combine [the prior art] references") A failure to heed these mandates results in an improper obviousness rejection of a claim based on selective hindsight wherein Applicant's claims are used against him as a map to navigate through isolated and unrelated disclosures in the prior art.

(3) Level of Ordinary Skill in the Pertinent Art

As recognized in Section 2141.03 of the MPEP, the prior art itself can indicate the level of ordinary skill in the art. In this case, the prior art Gardner reference is written to persons having ordinary skill in the art who work in hospitals and directs those persons to conduct audits to prevent the sale of pharmaceuticals that have already been purchased at an "own use" discount to brokers who supply small drugstores. Based on this teaching to persons having ordinary skill in the art, Applicant respectfully submits that a person having ordinary skill in the art would not have found claim 1 obvious at the time of invention because Gardner directs such a person to limit the sale of "own use"-discounted pharmaceuticals, not expand such sales to new buyers who Gardner expressly disparages as "questionable brokers" who are seeking to induce hospitals into committing illegal acts.

(4) Objective Evidence of Nonobviousness

Applicant further submits that the Gardner reference serves as objective evidence of nonobviousness for claim 1. As stated above, Gardner teaches that an audit process should be employed to prevent the sale of pharmaceuticals that have already been purchased at an "own use" discount to brokers who supply small drugstores. Gardner makes this teaching even though such small drugstores could be supplying nursing homes with pharmaceuticals, as reflected in the positioning of the "pharmacies" and "nursing home" triangles in the Pyramid Cube Scheme of Exhibit 1. Claim 1, contrary to the teachings of Gardner, is directed toward

an auditing process that brings the “own use” discount to nursing homes who receive their pharmaceuticals from such pharmacies.

Therefore, for the foregoing reasons, Applicant respectfully submits that claim 1 and all of its dependent claims are nonobvious in view of the Colella/Gardner combination.

V. The Colella and Gardner references also fail to render independent claim 62 obvious.

Applicant also notes that independent claim 62 is nonobvious over the Colella/Gardner combination for similar reasons as expressed in connection with claim 1. Applicant further notes that claim 62 is limited to “determining an ‘own use’ discount status for a ***proposed ‘own use’ purchase***” of pharmaceuticals by a buyer, wherein the “buyer comprises at least one selected from the group consisting of (1) a retail pharmacy that supplies pharmaceuticals to at least one hospital, nursing home, or long term health care facility where said at least one patient resides, and (2) an entity comprising a plurality of said retail pharmacies.” Applicant further notes that the Colella/Gardner combination fails to address the concept of auditing ***proposed*** orders to assess their “own use” discount eligibility. Instead, the Gardner/Colella combination teaches that Colella’s inventory tracking system should be used to conduct an audit for assessing whether pharmaceuticals already purchased at an “own use” discount are being diverted from inventory to “questionable brokers”. Therefore, Applicant respectfully submits that independent claim 62 and all of its dependent claims are also nonobvious in view of the Colella/Gardner combination.

VI. The Colella and Gardner references also fail to render dependent claim 65 obvious.

Dependent claim 65 further limits claim 62 (by way of claim 63) to a buyer that is a **retail** pharmacy. As such, Applicant respectfully submits that claim 65 is patentable over the Colella/Gardner combination for the same reasons expressed above in connection with claims 1 and 62. Applicant further notes that the Final Office Action misinterprets the Colella reference in its rejection of claim 65 because Colella addresses the in-house pharmacies of hospitals (i.e., closed pharmacies) rather than a **retail** pharmacy which supplies a hospital, nursing home, or long term health care facility, as required by claim 65.

VII. The Colella and Gardner references also fail to render dependent claim 66 obvious.

Dependent claim 66 further limits claim 62 (by way of claim 63) to a buyer that is an entity comprising a plurality of retail pharmacies which supply a hospital, nursing home, or long term health care facility. As such, Applicant respectfully submits that claim 66 is patentable over the Colella/Gardner combination for the same reasons expressed above in connection with claims 1 and 62. Applicant further notes that the Final Office Action misinterprets the Colella reference in its rejection of claim 66 because Colella addresses the in-house pharmacies of hospitals (i.e., closed pharmacies) rather than a retail pharmacy which supplies a hospital, nursing home, or long term health care facility, as required by claim 66.

VIII. The Colella and Gardner references also fail to render independent claim 30 obvious.

Independent claim 30 is directed toward an auditing system having a processor configured to execute software to perform an "own use" audit on order data, wherein the software is "configured to (1) confirm whether said buyer is any of a group consisting of (a) an entity comprised of at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (b) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home..." As such, Applicant respectfully submits that claim 30 is patentable over the Colella/Gardner reference for the same reasons expressed above in connection with claim 1.

IX. The Colella and Gardner references fail to render independent claim 76 obvious because those references fail to render obvious the concept of, as part of an auditing process assessing whether a pharmaceutical order is entitled to an "own use" discount, adjusting the order's quantity such that the order's adjusted quantity matches a quantity that is supported by the "associated report" which evidences a need "own use" pharmaceuticals.

The Final Office Action rejected independent claim 76 for obviousness based on the combination of the Colella and Gardner references. The rejection of claim 76 incorporates the rationale for rejecting claims 1 and 28. In rejecting claim 28, the Final Office Action asserted that col. 6, line 65 through col. 7, line 28 and col. 8, lines 59-67 of Colella disclose the concept of adjusting orders to match a report that summarizes the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by the buyer.

Thus, with respect to the scope and content of the prior art, Applicant repeats the observations made above regarding Colella and Gardner. Applicant further notes that the passages cited in Colella in the rejection of claim 28 pertain to features of Colella that track pharmaceutical usage recorded through DDMs such that orders with the appropriate quantities are placed with the distributor. (See Colella; col. 6, line 65 – col. 7, line 28; col. 8, lines 59-67).

The paragraph at col. 6, line 57 through col. 7, line 6 of Colella addresses the use of a percentage threshold to determine when it is time to order a new “unit” of drugs. Thus, if the drug is kept in 100 count bottles, the use of an 80% threshold would operate such that a new unit of that drug is not ordered until 80 tablets have been reported as consumed through the DDMs.

The paragraphs at col. 7, lines 7-20 of Colella address the use of a “track holdover” field for tracking scenarios where an order results in a drug supply greater than the expressed need. Thus, from the example above, where a 100 count bottle of tablets was ordered because 80 tablets had been reported as consumed through the DDMs, a holdover count of 20 tablets will be applied to future usage to determine when a new order is needed. Thus, with a holdover quantity of 20, the DDMs would need to report the consumption of 100 tablets before hitting the 80% threshold again.

The paragraphs at col. 7, lines 21-28 of Colella address the use of the “track holdover” field for tracking scenarios where a need is expressed for a drug that is below the ordering threshold, wherein the system will remember this need and apply it toward future needs of the drug. Thus, if a need is expressed for only 20 tablets, no order will be placed because of the 80% threshold. However, if the DDMs later report the consumption of an additional 60 tablets, the system will apply the holdover quantity of 20 to the new quantity of 60 to find that a new order should be placed because the 80% threshold has been reached.

There are a number of differences between claim 76 and the Colella/Gardner combination. First, Applicant notes that the orders in Colella are not audited to assess whether they are entitled to an “own use” discount because they are presumed to be entitled to such a discount by virtue of the fact that a hospital’s in-house pharmacy is placing the order. The addition of Gardner to Colella operates to perform audits on orders that have already been filled to assess whether diversion from a hospital’s inventory is occurring. The role of this

audit is not to adjust the quantity in an order because Colella's system is already configured to generate orders that closely match patient needs by basing orders on the inputs through the DDMs.

Second, claim 76 requires that an order for a quantity of a pharmaceutical be received, and further requires that this order be adjusted as a result of the "own use" auditing process. Colella, on the other hand, describes a system whereby the orders are initially formulated with the appropriate quantities such that no further adjustments are necessary. As taught by Colella, the "track holdover" quantity that is maintained by the inventory management system allows any overstock amounts "to be deducted *before an order is placed.*" (See Colella, col. 8, lines 59-67 (emphasis added)). There is simply no teaching, suggestion, or motivation in the record for a method which (1) audits a pharmaceutical order that has already been placed to determine whether the order is supported by the "associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer", and (2) responsive to a determination that the order is not supported by the associated report, adjusting the order such that it is supported by the associated report (e.g., lowering the order quantity). Moreover, the Final Office Action provides no rationale as to why a person having ordinary skill in the art would find claim 76 obvious given the lack of teachings, suggestions, and motivations in Colella and Gardner as to order adjustment.

Therefore, Applicant respectfully submits that the obviousness rejection of claim 76 is improper and must be reversed.

X. The Colella and Gardner references also fail to render independent claim 75 obvious.

Applicant notes that independent claim 75 includes similar limitations to claim 76. Claim 75 further recites that the order adjustment involves adjusting the order's quantity to a subquantity thereof as a result of the auditing process. As explained above in connection with claim 76, the Colella/Gardner references are silent with respect to the concept of adjusting an order's quantity based on an audit process because the Colella/Gardner combination operates to produce orders that do not need adjustment since the order is originally placed with a quantity that is based on an inventory management system that closely track the needs of patients within a hospital. Gardner thus applies to the Colella system only to audit existing inventory

to detect whether diversion is occurring (e.g., diversion of the overstock amounts defined by the “track holdover” parameters).

XI. The Colella and Gardner references also fail to render dependent claims 28, 48, 68 and 73 obvious.

Applicant further notes that dependent claims 28, 48, 68, and 73 also recite limitations similar to claims 75 and 76. As such, Applicant respectfully submits that claims 28, 48, 68, 73, 75, and 76 (and all claims dependent therefrom) are patentable over the Colella/Gardner combination for the reasons expressed above in connection with claims 75 & 76.

XII. The Colella and Gardner references also fail to render dependent claims 29, 49, and 77 obvious.

Dependent claims 29, 49, and 77 require that a “stand by requirement” for the buyer be calculated. The specification discusses this feature at page 18, line 7 – page 19, line 5 and at page 25, lines 4-14 (see also Figure 9). Through this feature, adjustments to orders can be made so that a nursing home supplied through the buyer will have a sufficient stock of pharmaceuticals on hand to meet the demand of expected new patients.

The Final Office Action cites Colella at col. 6, line 65 – col. 7, line 28 and col. 8, lines 59-67 for disclosing this feature. However, these passages, which are summarized above in Section IX do not involve calculating stand by requirements, but rather relate to setting thresholds and holdover quantities that affect how orders are placed. As such, Applicant respectfully submits that the rejection of claims 29, 49, and 77 is in error because the Final Office Action provides no rationale as to why a person having ordinary skill in the art would modify the order threshold percentage and holdover tracking features of Colella to perform a stand by requirement calculation.

XIII. The Colella and Gardner references fail to render independent claim 16 obvious because those references fail to render obvious the concept of using two reports to assess whether a given pharmaceutical order is entitled to an “own use” discount.

Claim 16 is directed to a method that improves the reliability of an “own use” status determination for an order from a buyer by requiring that both a “first associated report summarizing the “own use” pharmaceutical needs of at least one patient who is supplied with

pharmaceuticals" by the buyer and a "second associated report summarizing the "own use" pharmaceutical needs of said at least one patient who is supplied with pharmaceuticals" by the buyer be analyzed to determine whether the order qualifies for an "own use" discount.

With respect to the scope and content of the prior art, Colella discloses that a patient's drug needs are tracked as a result of data entry by health care providers through the DDMs. (See Colella; col. 4, lines 1-9). Colella further teaches that the DIMS program running on the CPC will aggregate the patient needs reported through the DDMs to generate a purchase order for drugs to be placed with the DCC. (See Colella, col. 4, lines 10-26; col. 5, lines 33-43). Gardner states that purchase orders should be inspected for "lack of documentation" to assess whether diversion may be occurring, but does not elaborate on what documentation should be inspected. (See Gardner; p. 74).

Applicant respectfully submits that, at best, a person having ordinary skill in the art would be motivated by Gardner to inspect Colella's purchase orders against the DDM records to assess whether any diversion of the hospital's inventory may be occurring. There is no teaching, suggestion, or motivation in either Colella or Gardner for using a second report that summarizes the patient's drug needs to add reliability to the audit process through redundancy. Moreover, the Final Office Action fails to provide any reason for a person having ordinary skill in the art to analyze orders against not only a report based on the DDM records but also against a second report independently of the teachings, suggestions, and motivations found in the Colella and Gardner references. Instead, the Final Office Action contends that Colella discloses the use of the second report at col. 8, lines 41-67, wherein this second report is analyzed to assess whether it supports the order. However, Applicant interprets this passage as describing the interface screen for reviewing "items that have been ordered through the DDM system". (See Colella; col. 8, lines 41-42; Figure 6). Thus, the information contained in the interface screen of Figure 6 relates to an already placed order and is not used to make a status determination as to whether the buyer qualifies for an "own use" discount. Once again, Colella's orders are presumed to be entitled to the "own use" discount so no analysis would be necessary to make the status determination of claim 16. Furthermore, Applicant notes that the information in the interface screen of Figure 6 does not include sufficient information from which to judge whether an order is entitled to an "own use" discount. It can be seen that the

interface screen of Figure 6 *does not in fact indicate the quantity of each item that has been ordered* and thus would not be useful for the analyzing step recited in claim 16. While the screen indicates the previous purchase order (PO) in which each listed drug was ordered, the screen *fails to identify the actual quantity ordered for each item*. The "TR QUAN" field is described at col. 8, lines 59-67 as identifying only the holdover quantity for the item, which represents the current inventory overstock. For example, item 1015130 is listed with a TR QUAN value of "100 20", which Applicant interprets as a holdover overstock of 20 tablets relative to a 100 count bottle. (See Colella; col. 7, lines 12-20). The "ORD" field is described as identifying the ordering threshold percentage for the associated item. (See Colella; col. 9, lines 1-4). Applicant further notes that the "ITEM" field and the "STK#" field are used to list the identifiers for the drug referenced in the "DESCRIPTION" field, as used by the DDMs and DCC respectively. (See Colella; col. 8, lines 50-54; col. 6, lines 6-7). Thus, Applicant interprets the ITEM and STK# fields as also failing to convey the actual quantity of each drug in a given purchase order. This failure is understandable as Colella discloses that the role of the interface screen of Figure 6 is not for comparison against orders, but rather its "purpose ... is to allow review, and if necessary, adjustments to the carryover quantity and ordering threshold for a particular item." (See Colella; col. 8, lines 41-44). Therefore, Applicant respectfully submits that the Final Office Action is in error when it asserted that Colella discloses the analysis of two reports to assess whether the reports support the order; as such, Applicant respectfully submits that claim 16 is patentable over the Colella/Gardner combination because the Final Office Action provides no rationale as to why a person having ordinary skill in the art would find it obvious to analyze two reports summarizing a patient's "own use" needs when assessing whether a pharmaceutical order is entitled to an "own use" discount.

XIV. The Colella and Gardner references fail to render dependent claim 17 obvious.

Dependent claim 17 further recites the step of "placing said order with a pharmaceutical seller in response to said status determination identifying said buyer as qualified for said "own use" discount, said order having a price reduced by an "own use" discount." This claim is further distinguishable over the Colella/Gardner combination. As indicated above, the

interface screen of Figure 6 which the Examiner has equated to the "second associated report" of claim 16 is described by Colella as pertaining to items that have already been ordered. However, with claim 17, the order is not placed until after the two reports have been analyzed and a status determination as to the "own use" discount eligibility is made. This represents an entirely different mode of operation than the Colella/Gardner combination, which presupposes that orders are entitled to "own use" discounts, and wherein audits are conducted on the hospital's inventory to assess whether an diversion has been occurring after orders have been filled. Therefore, Applicant respectfully submits that claim 17 is also patentable over the Colella/Gardner combination.

XV. The Colella and Gardner references fail to render independent claim 69 obvious.

Independent claim 69 includes limitations similar to claim 16, namely, claim 69 requires that the "own use" audit be based on at least two types of audit data. As such, because Gardner is silent as to the "documentation" to be used for inspecting purchase orders and because Colella discloses only one form of potential audit data (the DDM records), Applicant respectfully submits that claim 69 is also patentable over the Gardner/Colella combination for the reasons set forth above with respect to claim 16.

XVI. The Colella and Gardner references fail to render dependent claims 70 and 79 obvious.

Dependent claims 70 and 79 require that the "own use" audit utilize a "retail pharmacy listing". As previously explained in connection with claim 1, the cited references are silent with respect to how retail pharmacies can obtain "own use" discounts. In this silence, the cited references further fail to render obvious the concept of using the retail pharmacy listings recited in claims 70 and 79 to establish that an order is entitled to an "own use" discount. Therefore, Applicant further submits that the obviousness rejection of claims 70 and 79 are in error and must be reversed.

XVII. The Colella and Gardner references fail to render dependent claim 64 obvious.

Claim 64 requires that the information used to assess the order's entitlement to an "own use" discount comprises "information from at least one POS" and "information from at

least one MAR". POSs and MARs are described in the patent application with reference to Figures 3-4. The citations by the Examiner to Colella for rejecting claim 64 point not to POSs and MARs but rather to the interface screens of Figures 5-6. Therefore, Applicant respectfully submits that the obviousness rejection of claim 64 is deficient because the Examiner has announced no rationale for a person having ordinary skill in the art to use POSs and MARs for an audit. Furthermore, the Examiner has misinterpreted claim 64 to require information from a POS or information from an MAR. This error by the Examiner also establishes the error of claim 64's obviousness rejection.

XVIII. The Colella, Gardner, and Spurgeon references fail to render claims 2-8, 11, 14, and 38-44 obvious.

For the same reasons expressed above in connection with the claims from which claims 2-8, 11, 14, and 38-44 depend, Applicant respectfully submits that the obviousness rejections of claims 2-8, 11, 14, and 38-44 are in error and must be reversed. The Spurgeon reference relates to a system for processing health care insurance information. Spurgeon was cited by the Examiner only in connection with claim limitations relating to computer networking and file format conversions. (See Final Office Action; p. 27-36). As such, Spurgeon is not germane to the issues discussed above in connection with Colella and Gardner regarding "own use" audits.

viii. Claims Appendix:

1. A method for processing orders for "own use" discount pharmaceuticals, said method comprising the steps of:

receiving an order comprising a request from a buyer for a quantity of a type of pharmaceutical, wherein said buyer comprises one from a group consisting of (1) an entity comprising at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (2) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, said at least one nursing home having at least one patient needing said type of pharmaceutical;

receiving an associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer;

comparing said order with said associated report to determine whether said associated report supports said order; and

responsive to said comparison, making a status determination as to whether said buyer qualifies for purchasing said quantity of said type of pharmaceutical at a price reduced by an "own use" discount.

2. The method of claim 1 wherein the step of receiving said order further comprises receiving said order on a computer as a transmission over the internet.

3. The method of claim 2 wherein the step of receiving said associated report further comprises receiving said report as at least one computer file, and wherein the comparison step is performed by a software program executed on said computer.

4. The method of claim 3 further comprising the step of converting said at least one computer file to a format readable by said software program.
5. The method of claim 2 further comprising the step of entering said associated report as data into said computer, and wherein the comparison step is performed by a software program executed on said computer.
6. The method of claim 2 further comprising the steps of:
receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer, said second associated report being received as at least one computer file; and
comparing said second associated report with said order or with said associated report using a computer; and
wherein the determination step further depends upon whether said second associated report supports said order.
7. The method of claim 6 wherein the comparing step between said second associated report and said order is performed by a software program executed on said computer, the method further comprising the step of converting said at least one computer file to a format readable by said software program.
8. The method of claim 2 further comprising the steps of:

receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer;
entering said second associated report as data into said computer; and
comparing said second associated report with said order or with said associated report using a computer; and
wherein the determination step further depends upon whether said second associated report supports said order.

9. The method of claim 1 further comprising the step of entering said order as data into a computer.

10. The method of claim 9 wherein the step of receiving said associated report further comprises receiving said report as at least one computer file, and wherein the comparison step is performed by a software program executed on said computer.

11. The method of claim 10 further comprising the step of converting said at least one computer file to a format readable by said software program.

12. The method of claim 9 further comprising the step of entering said associated report as data into said computer, and wherein the comparison step is performed by a software program executed on said computer.

13. The method of claim 9 further comprising the steps of:

receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer, said second associated report being received as at least one computer file; and

comparing said second associated report with said order or with said associated report using a computer; and

wherein the determination step further depends upon whether said second associated report supports said order.

14. The method of claim 13 wherein the comparing step between said second associated report and said order is performed by a software program executed on said computer, the method further comprising the step of converting said at least one computer file to a format readable by said software program.

15. The method of claim 9 further comprising the steps of:

receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer;

entering said second associated report as data into said computer; and

comparing said second associated report with said order using a computer; and

wherein the determination step further depends upon whether said second associated report supports said order.

16. A method for processing orders for "own use" discount pharmaceuticals, said method comprising the steps of:

receiving an order comprising a request from a buyer for a quantity of a type of pharmaceutical;

receiving a first associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer;

receiving a second associated report summarizing the "own use" pharmaceutical needs of said at least one patient who is supplied with pharmaceuticals by said buyer;

analyzing said first associated report and said second associated report to determine an extent to which they support said order; and

responsive to said determined extent, making a status determination as to whether said buyer qualifies for purchasing said quantity of said type of pharmaceutical at a price reduced by an "own use" discount.

17. The method of claim 16 further comprising the step of placing said order with a pharmaceutical seller in response to said status determination identifying said buyer as qualified for said "own use" discount, said order having a price reduced by an "own use" discount.

18. The method of claim 17 further comprising the step of sending either said first associated report or said second associated report, or both said first and second associated reports, to said pharmaceutical seller.

19. The method of claim 17 further comprising the step of allowing said pharmaceutical seller to have access to either said first associated report or said second associated report or both said first and second associated reports.

20. The method of claim 1 further comprising the step of placing said order with a pharmaceutical seller in response to said status determination identifying said buyer as qualified for said "own use" discount, said order having a price reduced by an "own use" discount.

21. The method of claim 20 further comprising the step of sending said associated report to said pharmaceutical seller.

22. The method of claim 20 further comprising the step of allowing said pharmaceutical seller to have access to said associated report.

23. The method of claim 20 further comprising the steps of generating a status report and sending said status report to said pharmaceutical seller.

24. CANCELED

25. The method of claim 20 further comprising the step of arranging for said pharmaceutical seller to directly ship an appropriate quantity of said type of pharmaceutical directly to one of a group consisting of:

an entity comprised of at least one retail pharmacy supplying pharmaceuticals to at least one nursing home, said at least one nursing home having at least one patient needing said type of pharmaceutical;

at least one retail pharmacy supplying pharmaceuticals to at least one nursing home, said at least one nursing home having at least one patient needing said type of pharmaceutical; and

at least one nursing home having at least one patient needing said type of pharmaceutical.

26. CANCELED

27. The method of claim 1 further comprising the step of generating a status report.

28. The method of claim 1 further comprising, in response to said comparison resulting in a status determination that said buyer does not qualify for said discount, adjusting said order so that said order is supported by said associated report.

29. The method of claim 28 wherein the step of adjusting said order comprises calculating a stand by requirement for said buyer.

30. A pharmaceutical order auditing system for determining whether a pharmaceutical buyer qualifies for an "own use" discount, said pharmaceutical order auditing system comprising:

a first input for receiving pharmaceutical order data, said order data comprising a type of pharmaceutical, a quantity of said type of pharmaceutical, and a buyer requesting said quantity of said type of pharmaceutical;

a second input for receiving audit data, said audit data being sufficient for a status determination of whether said buyer qualifies for purchasing said quantity at a price reduced by an "own use" discount;

a processor;

software that is executed on said processor, the software being configured to (1) confirm whether said buyer is any of a group consisting of (a) an entity comprised of at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (b) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, said at least one nursing home having at least one patient needing said type of pharmaceutical, and (2) compare said order data with said audit data to make a status determination whether said buyer qualifies for purchasing said quantity at said reduced price, said status determination depending upon said confirmation and said comparison between said order data and said audit data; and

an output for communicating said status determination to a user.

31. CANCELED

32. The pharmaceutical order auditing system of claim 30 wherein said audit data is gathered from one of a group consisting of:

a listing compiled by each of said retail pharmacies, each of said listings containing a record of pharmaceuticals requested by each of said nursing homes;

a physicians order sheet for each of said patients in each of said nursing homes; and

a medication administration record for each of said patients in each of said nursing homes.

33. The pharmaceutical order auditing system of claim 30 further comprising a third input for receiving additional audit data, said additional audit data being sufficient for a status determination of whether said buyer qualifies for purchasing said quantity at a price reduced by an "own use" discount, and wherein said software is further configured to compare said additional audit data with said order data or with said audit data in making said status determination, said status determination further depending upon said additional audit data comparison.

34. The pharmaceutical order auditing system of claim 33 wherein said additional audit data is gathered from one of a group consisting of:

a listing compiled by each of said retail pharmacies, each of said listings containing a record of pharmaceuticals requested by each of said nursing homes;

a physicians order sheet for each of said patients in each of said nursing homes; and

a medication administration record for each of said patients in each of said nursing homes.

35. The pharmaceutical order auditing system of claim 30 wherein said audit data comprises a type of pharmaceutical, an amount of said type of pharmaceutical requested by each of said retail pharmacies, and each of said nursing homes requesting each of said amounts from each of said retail pharmacies, and wherein said software compares said order data with said audit data, said status determination depending upon whether said comparison between said order data and said audit data results in a sufficient correlation between said order data and said audit data for said buyer to qualify for said discount.

36. The pharmaceutical order auditing system of claim 35 further comprising a third input for receiving additional audit data, said additional audit data comprising a type of pharmaceutical, an amount of said type of pharmaceutical requested by each of said retail pharmacies, and each of said nursing homes requesting each of said amounts from each of said retail pharmacies, and wherein said software compares said additional audit data with said

order data or with said audit data, said status determination further depending upon said additional audit data comparison.

37. The pharmaceutical order auditing system of claim 35 wherein said order data further comprises a plurality of identifiers for each of said patients needing said quantity of said type of pharmaceutical, wherein said audit data further comprises a plurality of identifiers for each of said patients in each of said nursing homes needing each of said amounts of said type of pharmaceuticals, and wherein said software is further configured to compare said patient identifiers in said audit data with said patient identifiers in said order data, said status determination further depending upon whether said patient identifier comparison results in a sufficient number of matches between said audit data patient identifiers and said order data patient identifiers.

38. The pharmaceutical order auditing system of claim 35 further comprising a converter configured to convert said audit data to a common format.

39. The pharmaceutical order auditing system of claim 38 wherein said audit data is gathered from one of a group consisting of:

a listing compiled by each of said retail pharmacies, each of said listings containing a record of pharmaceuticals requested by each of said nursing homes;

a physicians order sheet for each of said patients in each of said nursing homes; and

a medication administration record for each of said patients in each of said nursing homes.

40. The pharmaceutical order auditing system of claim 38 further comprising a third input for receiving additional audit data, said additional audit data comprising a type of pharmaceutical, an amount of said type of pharmaceutical requested by each of said retail pharmacies, and each of said nursing homes requesting each of said amounts from each of said retail pharmacies, and wherein said software compares said additional audit data with said order data or with said audit data, said status determination further depending upon said additional audit data comparison.

41. The pharmaceutical order auditing system of claim 40 wherein said additional audit data is gathered from one of a group consisting of:

a listing compiled by each of said retail pharmacies, each of said listings containing a record of pharmaceuticals requested by each of said nursing homes;

a physicians order sheet for each of said patients in each of said nursing homes; and

a medication administration record for each of said patients in each of said nursing homes.

42. The pharmaceutical order auditing system of claim 40 wherein said converter is further configured to convert said additional audit data to a common format.

43. The pharmaceutical order auditing system of claim 40 wherein said order data further comprises a plurality of identifiers for each of said patients needing said quantity of said type of pharmaceutical, wherein said additional audit data further comprises each of a plurality of identifiers for said patients in each of said nursing homes needing each of said amounts of said type of pharmaceuticals, and wherein said software is further configured to compare said patient identifiers in said additional audit data with said patient identifiers in said order data, said status determination further depending upon whether said patient identifier comparison results in a sufficient number of matches between said additional audit data patient identifiers and said order data patient identifiers.

44. The pharmaceutical order auditing system of claim 38 wherein said order data further comprises a plurality of identifiers for each of said patients needing said quantity of said type of pharmaceutical, wherein said audit data further comprises a plurality of identifiers for each of said patients in each of said nursing homes needing each of said amounts of said type of pharmaceuticals, and wherein said software is further configured to compare said patient identifiers in said audit data with said patient identifiers in said order data, said status determination further depending upon whether said patient identifier comparison results in a sufficient number of matches between said audit data patient identifiers and said order data patient identifiers.

45. The pharmaceutical order auditing system of claim 30 wherein said output is communicated to said user as a status report.

46. The pharmaceutical order auditing system of claim 30 further comprising a third input for receiving additional audit data, said additional audit data being sufficient for a status determination of whether said buyer qualifies for purchasing said quantity at a price reduced by an "own use" discount, and wherein said software is further configured to compare said additional audit data with said order data or with said audit data in making said status determination, said status determination further depending upon said additional audit data comparison.

47. The pharmaceutical order auditing system of claim 30 wherein said software is further configured to allow for a tolerance in making said status determination.

48. The pharmaceutical order auditing system of claim 30 wherein said software is configured to adjust said order so that there is a sufficient match between said adjusted order and said audit data if said buyer does not qualify for said buyer does not qualify for said discount on the basis of said unadjusted order.

49. The pharmaceutical order auditing system of claim 48 wherein said software is configured to calculate a stand by requirement for said buyer if said order needs adjustment.

50-61. CANCELED

62. A computer-implemented method for processing pharmaceutical orders to determine whether said orders qualify for an "own use" discount, said method comprising:

determining an "own use" discount status for a proposed "own use" purchase by a buyer of a quantity of a type of pharmaceutical on the basis of a comparison between the proposed purchase and information that summarizes at least one "own use" pharmaceutical need of at least one patient who is supplied with the pharmaceutical by the buyer; and

wherein said buyer comprises at least one selected from the group consisting of (1) a retail pharmacy that supplies pharmaceuticals to at least one hospital, nursing home, or long term health care facility where said at least one patient resides, and (2) an entity comprising a plurality of said retail pharmacies.

63. The method of claim 62 wherein said information comprises at least one selected from the group consisting of information from a retail pharmacy that summarizes a pharmaceutical need by at least one hospital, nursing home, or long term health care facility where said at least one patient resides, information from at least one physician order sheet (POS), and information from at least one medication administration record (MAR).

64. The method of claim 63 wherein said information comprises information from at least one POS and information from at least one MAR.

65. The method of claim 63 wherein said buyer comprises said retail pharmacy.

66. The method of claim 63 wherein said buyer comprises said entity.

67. CANCELED

68. The method of claim 63 further comprising:

if said quantity for said proposed purchase does not qualify for an "own use" discount, (1) determining, on the basis of said comparison, a subquantity of said quantity that does qualify for said "own use" discount and (2) adjusting said quantity for said proposed purchase to match said subquantity.

69. A system for determining whether a pharmaceutical buyer qualifies for an "own use" discount, said system comprising:

a computer configured to perform an "own use" audit on a pharmaceutical order to determine whether said order qualifies for an "own use" discount, said audit being based on at least two types of audit data that are compared to said order.

70. The system of claim 74 further comprising:

a second computer in communication with said computer via a network, said second computer being configured to provide said computer with said retail pharmacy listing, and

wherein the computer is further configured to perform said "own use" audit by comparing said order with said said retail pharmacy listing.

71. The system of claim 70 wherein said nursing home data comprises at least one selected from the group consisting of information from a physician order sheet (POS) corresponding to said at least one patient and information from a medication administration record (MAR) corresponding to said at least one patient.

72. The system of claim 71 wherein said buyer is one of a group consisting of:

an entity comprising a plurality of retail pharmacies that supply pharmaceuticals to at least one hospital, nursing home, or long term health care facility;

at least one retail pharmacy that supplies pharmaceuticals to at least one hospital, nursing home, or long term health care facility;

at least one hospital;

at least one nursing home; and

at least one long term health care facility.

73. The system of claim 69 wherein said order comprises an order for a quantity of pharmaceuticals, and wherein the computer is further configured to perform said "own use" audit by:

in response to said audit resulting in a determination that said quantity for said order does not qualify for an "own use" discount, determining whether a subquantity of said quantity does qualify for said "own use" discount; and

in response to said subquantity determining step resulting in a determination that a subquantity of said quantity does qualify for said "own use" discount, adjusting said quantity for said order to match said subquantity.

74. The system of claim 69 wherein said at least two types of audit data comprise:

a retail pharmacy listing that summarizes the pharmaceutical needs of a nursing home to which that retail pharmacy supplies pharmaceuticals; and

data from the nursing home that summarizes a pharmaceutical need of at least one patient of that nursing home.

75. A system for determining whether a pharmaceutical buyer qualifies for an "own use" discount, said system comprising:

a computer configured to perform an "own use" audit on a pharmaceutical order to determine whether said order qualifies for an "own use" discount;

wherein said order comprises an order for a quantity of pharmaceuticals; and

wherein the computer is further configured to perform said "own use" audit by: (1) in response to said audit resulting in a determination that said quantity for said order does not qualify for an "own use" discount, determining whether a subquantity of said quantity does qualify for said "own use" discount, and (2) in response to said subquantity determining step

resulting in a determination that a subquantity of said quantity does qualify for said "own use" discount, adjusting said quantity for said order to match said subquantity.

76. A method for processing orders for "own use" discount pharmaceuticals, said method comprising the steps of:

receiving an order comprising a request from a buyer for a quantity of a type of pharmaceutical;

receiving an associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer;

comparing said order with said associated report to determine whether said associated report supports said order;

responsive to said comparison, making a status determination as to whether said buyer qualifies for purchasing said quantity of said type of pharmaceutical at a price reduced by an "own use" discount; and

responsive to said comparison resulting in a status determination that said buyer does not qualify for said discount, adjusting said order so that said order is supported by said associated report.

77. The method of claim 76 wherein the step of adjusting said order comprises calculating a stand by requirement for said buyer.

78. The method of claim 62 wherein said information comprises at least two selected from the group consisting of information from a retail pharmacy that summarizes a pharmaceutical need by at least one hospital, nursing home, or long term health care facility where said at least one patient resides, information from at least one physician order sheet (POS), and information from at least one medication administration record (MAR).

79. The method of claim 16 wherein said first associated report comprises listing from a retail pharmacy that summarizes the pharmaceutical needs of a nursing home to which that retail pharmacy supplies pharmaceuticals, and wherein said second associated report comprises data from the nursing home that summarizes a pharmaceutical need of at least one patient of that nursing home.

80. The method of claim 79 wherein the second associated report data comprises data from a physician order sheet (POS) or data from a medication administration record (MAR).

Application No. 09/710,227
Attorney Docket No. 66790-6411

ix. Evidence Appendix:

Enclosed herewith as Exhibits A-C, respectively, are copies of the Colella, Gardner, and Spurgeon references cited by the Examiner in the first Office Action and the Final Office Action.

Application No. 09/710,227
Attorney Docket No. 66790-6411

x. Related Proceedings Appendix:

None.

For the foregoing reasons, Applicant respectfully submits that the Examiner's rejections as to all pending claims in this patent application are in error and must be reversed. Favorable action is respectfully requested.

Respectfully submitted,

Thompson Coburn LLP

By: 

Benjamin L. Volk, Jr.
Reg. No. 48,017
One US Bank Plaza
St. Louis, MO 63101-1693
(314) 552-6000
(314) 552-7000 (fax)



US006003006A

United States Patent [19]
Colella et al.

[11] **Patent Number:** **6,003,006**
[45] **Date of Patent:** ***Dec. 14, 1999**

[54] **SYSTEM OF DRUG DISTRIBUTION TO HEALTH CARE PROVIDERS**

[75] Inventors: **Salvatore J. Colella**, New Kensington, Pa.; **Stephen M. Lawrence**, Lexington, Ky.; **Gerald J. Widenhofer**, Dublin, Ohio

[73] Assignee: **Pyxis Corporation**, San Diego, Calif.

[*] Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

[21] Appl. No.: **08/762,041**

[22] Filed: **Dec. 9, 1996**

[51] Int. Cl.⁶ **G06F 17/60**

[52] U.S. Cl. **705/2; 364/479.07**

[58] Field of Search **705/2, 26, 28, 705/29, 30, 34, 14, 8; 364/479.07**

[56] **References Cited**

U.S. PATENT DOCUMENTS

5,406,475	4/1995	Kouchi et al.	705/8
5,611,051	3/1997	Pirelli	705/28
5,682,728	11/1997	DeBusk et al.	705/29
5,694,551	12/1997	Doyle et al.	705/26
5,712,989	1/1998	Johnson et al.	705/29
5,713,485	2/1998	Liff et al.	221/2

Primary Examiner—Emanuel Todd Voeltz

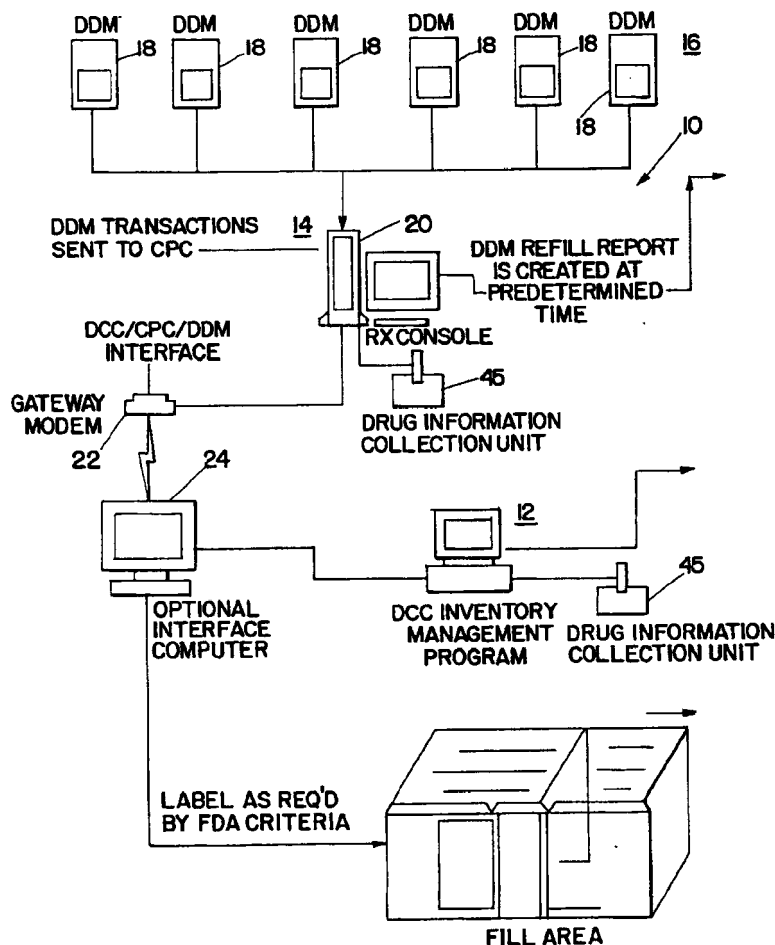
Assistant Examiner—Thomas A. Dixon

Attorney, Agent, or Firm—Michael D. Steffensmeier

[57] **ABSTRACT**

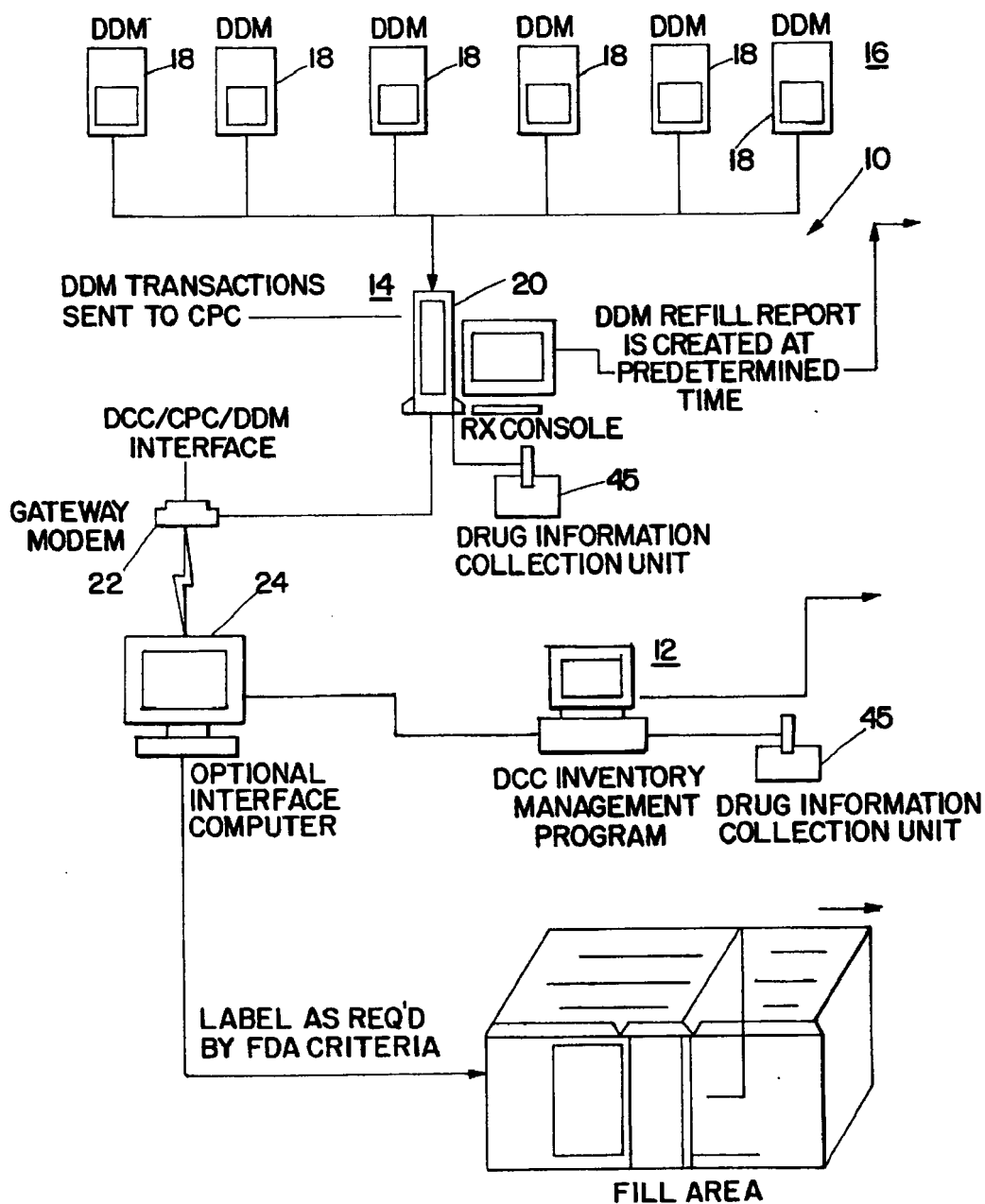
A system and method are described in which a drug distribution center operates a computer software drug inventory management program in electronic communication with a health care provider computer software program for drug distribution to patients. The system and method preferably incorporate low unit dose measure drug packaging including bar codes. The bar codes may be scanned into either software program for automatically tracking such information as drug lot numbers and expiration dates.

20 Claims, 8 Drawing Sheets



EXHIBIT

A

*Fig. 1A*

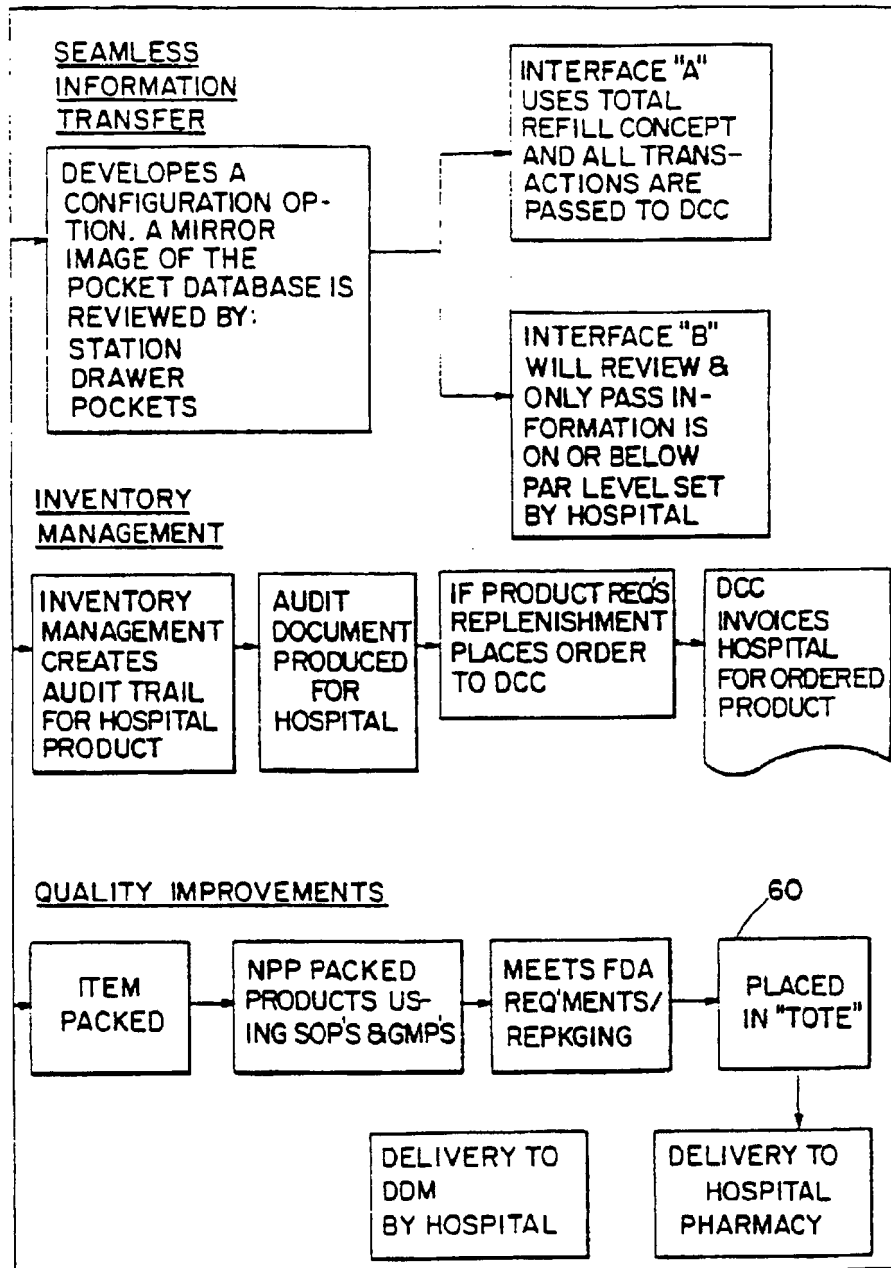
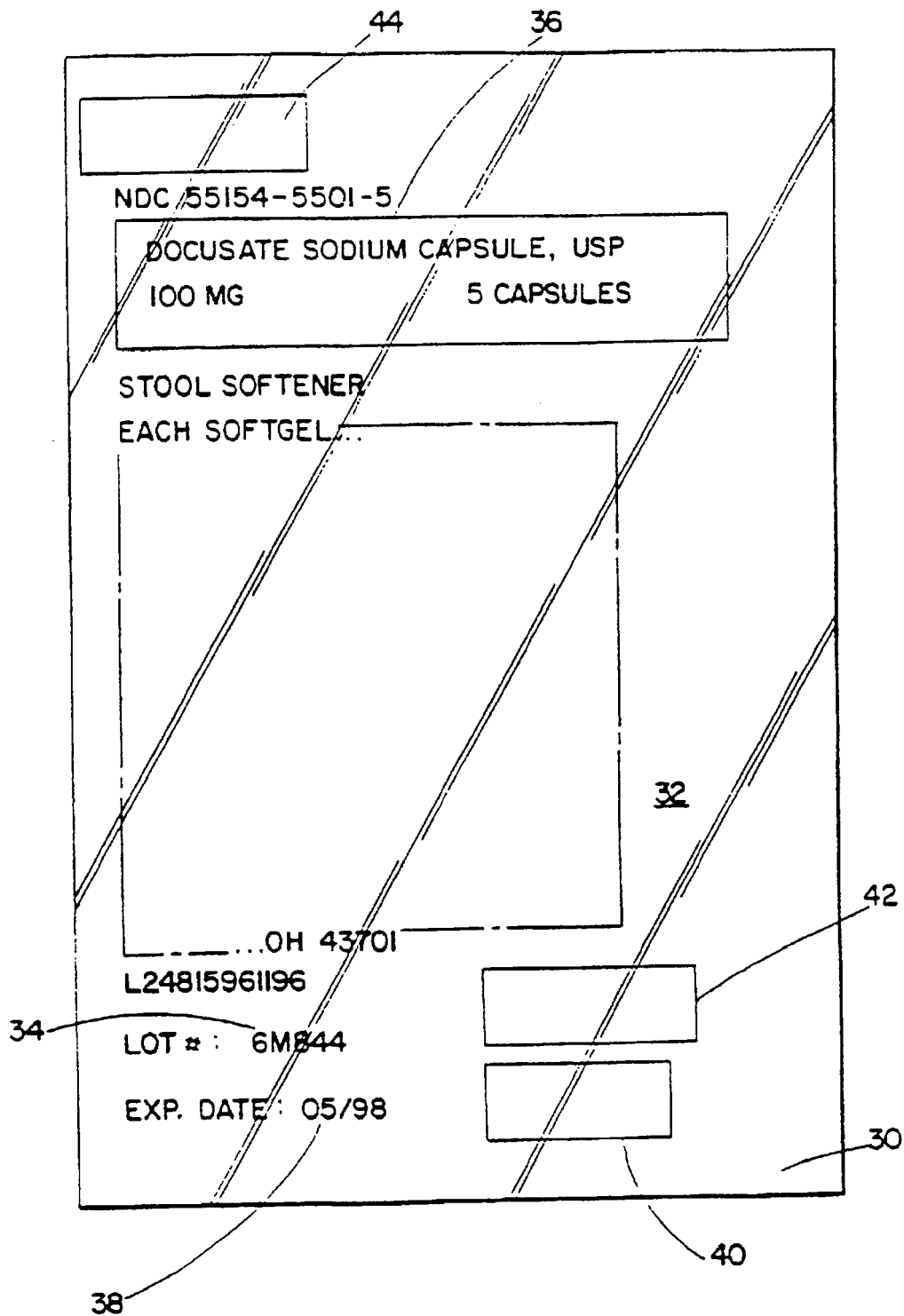


Fig. 1B



IDENTITY
SYSTEMS

DRUG NAME
XX MG
NDC 2345678901
LOT NO. ABCDE
EXP. DATE: DEC. 96

54

52

52

52

52

50

52

52

Fig. 3A

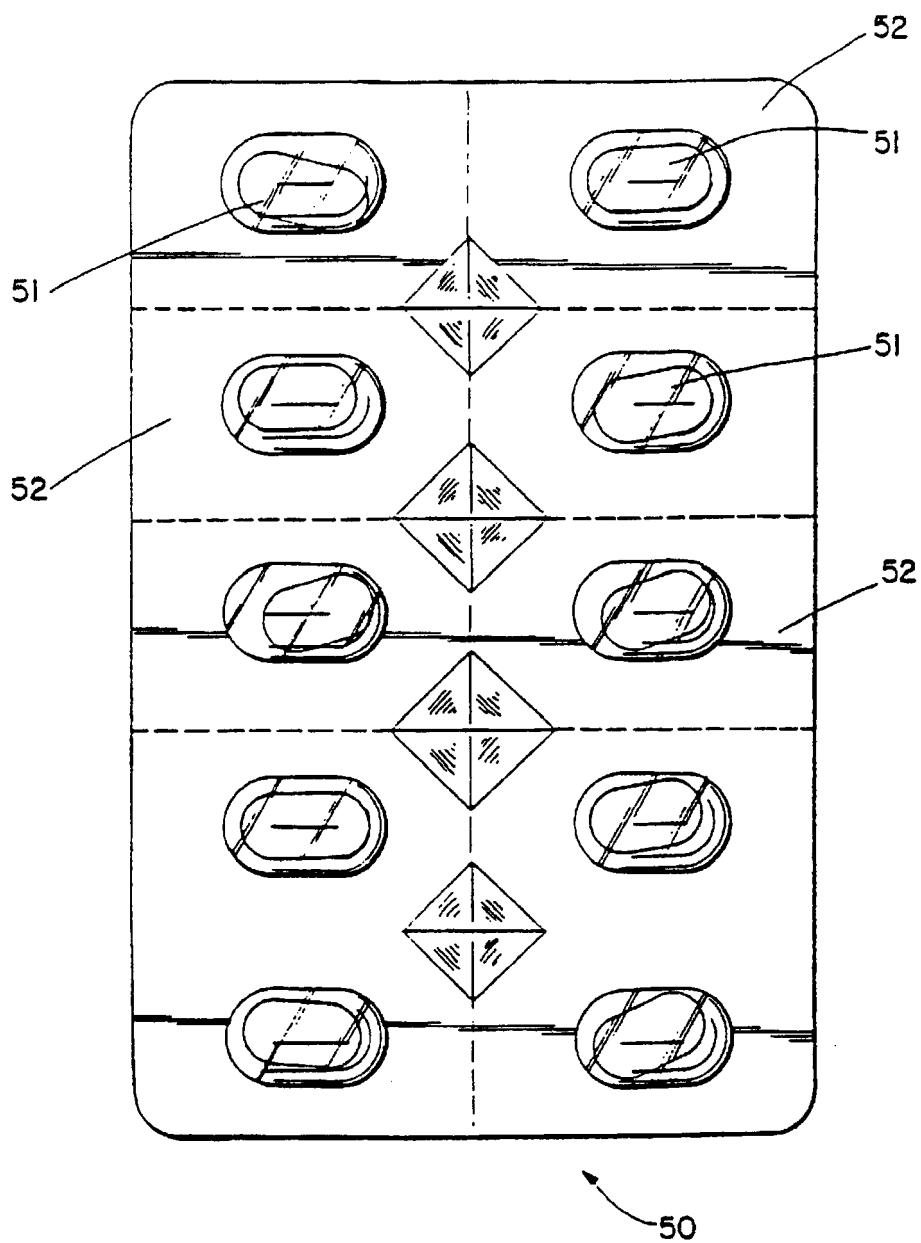


Fig. 3B

FILE	EDIT	ACTIVITIES	COMMUNICATIONS	REPORTS	TABLES	UTILITY	WINDOW	HELP

INTERFACE CONFIGURATION
- [] X

PURCHASE ORDER ITEMS
PROCESSING OPTIONS
REPORT OPTIONS
SETUP OPTIONS

PURCHASE ORDER

PO NUMBER [1000]

☒ CONFIRM PO NUMBER

☐ INCREMENT PO NUMBER

DEPARTMENT []

ORDERING OPTIONS

DEFAULT ORDERING THRESHOLD [80%]

☒ TRACK HOLD OVER ITEM QUANTITIES

☒ ROUND UP ORDER QUANTITIES

NARCOTIC OPTIONS

☒ TRACK NARCOTICS & GENERATE PO

☒ TRACK NARCOTICS & MANUALLY GENERATE PO

☒ DO NOT PROCESS NARCOTICS OPTIONS

BLANK NO. [12 34 56 78 90]

[]
~
[]
[]

Fig. 4

FILE

EDIT

ACTIVITIES

COMMUNICATIONS

REPORTS

TABLES

UTILITY

WINDOW

HELP

REINDEX TABLES

BACKUP DATA

RESTORE DATA

HANDHELD DOWNLOAD

IMPORT/EXPORT

INTERFACE SCREEN

INTERFACE NAME

IMPORT

VERSION

V20.4000

TYPE OF INTERF.

IMPORT PO DATA

COPY OUTPUT TO

OUTPUT FILE NAME

OVERWRITE OUTPUT FILE

APPEND TO OUTPUT FILE

INPUT DRIVE DIR.

C:\DDM\

INPUT FILE NAME

8.850

LAST UPDATE

08/05/1996 07:27:21AM

DESCR.

IMPORT PURCHASE ORDER DATA FROM A DDM SYSTEM.

4

▶

◻

↶

0

Fig. 5

FILE EDIT ACTIVITIES COMMUNICATIONS REPORTS TABLES UTILITY WINDOW HELP

□ □ ×

INTERFACE CONFIGURATION
□ □ ×

PURCHASE ORDER ITEMS
PROCESSING OPTIONS
REPORT OPTIONS
SETUP OPTIONS

PO#	ITEM	DESCRIPTION	STK#	CLASS	TR	QUAN	ORD
□	1015130	MAG OX TB 400 MG UD100	07605	0	100	20	50
□	1000	FERR SULF SC 325 MG UD L UD 100	07727	0	100	0	75
□	1000						
□	1000						
□	1000						
□	1000						
□	2000						
□	2000						

ITEM #
 PO #
 STK #

PRESS CTRL + TAB
TO EXIT GRID

Fig. 6

SYSTEM OF DRUG DISTRIBUTION TO HEALTH CARE PROVIDERS

BACKGROUND AND SUMMARY OF THE INVENTION

The present invention relates generally to a system for drug distribution to health care providers, and more particularly, the present invention relates to a system for drug information transfer, drug inventory management, and drug packaging, resulting in a unique system of drug distribution.

It has been known for health care providers, such as hospitals, to have a pharmacist or pharmacy department within the hospital to coordinate the dispensing of drugs to the patients of the health care institution. The pharmacists in such health care institutions have long been burdened with the increasingly complex record keeping and inventory management that results from hospitals caring for hundreds, if not thousands of patients every day. Various methods have been employed to assist a hospital's pharmacist or pharmacy department with maintaining accurate records while attempting to reduce the burden of managing all of the information associated with drug distribution. The pharmacist's responsibility has included: filling individual patient prescriptions on a daily basis; maintaining sufficient inventory of each drug in order to have enough quantities of the drug in hospital stock to administer to patients on a daily basis; tracking of drug interactions to prevent a patient from being given a drug that has adverse affects when combined with other drugs; accounting for the purchase of drugs for use in the hospital; accounting associated with the giving of drugs to individual patients; distributing the drugs to the appropriate nursing stations within the hospital to suit each station's daily demands; tracking of drug expiration dates to rid inventories of expired drugs; and tracking of drug lot numbers, for example in the event of a recall of a particular drug.

In recent years hospitals have been assisted with drug distribution management by the introduction of drug dispensing machines, such as the machines described in U.S. Pat. No. 5,014,875, entitled, Medication Dispenser Station and U.S. Pat. No. 5,460,294, entitled, Single Dose Pharmaceutical Dispenser Subassembly. Drug dispensing machines have effectively created branches of the hospital pharmacy department at each nursing station where the dispensing machines are located. The dispensing machines are frequently arranged to be electronically connected to a central computer system within the pharmacy department for tracking drugs that were to be administered to patients in that particular patient care area of the hospital. In this manner, hospitals have improved the manner in which drugs are dispensed to patients and the record keeping required by the pharmacy department has been simplified somewhat by each patient care area electronically reporting the variety and quantities of drugs dispensed from each drug dispensing machine.

Health care providers, such as hospitals, have traditionally purchased drugs from drug distributors, in bulk quantities (e.g., 100 single dose units of a particular variety of drug). While hospitals have purchased drugs in bulk due to manufacturer availability and then offered by the drug distributor, drugs are nevertheless dispensed at the health care institution on a patient-by-patient basis in low dose quantities. Therefore, hospitals have had to purchase and maintain large quantities of drugs until the drugs were eventually dispensed to the patients. Inventory turnover of drugs is usually

measured in days, weeks or more. During such time, the hospitals have had to incur the associated expense of carrying this large inventory of drugs. Frequently, the result has been independent management of such large quantities, including unexplained loss of portions of the drugs in inventory, and even theft of portions of the inventory. In addition, the pharmacy department of the hospital has had the extra burden of tracking the drugs dispensed for patient use, as well as tracking the drugs that the pharmacy is carrying in its inventory.

The present invention is designed to overcome several of the above mentioned problems associated with health care provider drug distribution. The present invention includes a unique form of drug packaging in combination with a computerized drug management software system. Low unit of measure quantities of a drug are packaged in an enclosure, such as a sealed plastic bag, and the bag is preferably marked with a lot number and a related lot number bar code for tracking the lot from which the drugs within that particular package were taken. The package may also include an expiration date and related expiration date bar code for tracking the expiration date of the drugs within the package. The package may also include an National Drug Code ("NDC") number and related NDC number bar code for identifying the variety of drug packaged within the enclosure. The package may also include further information regarding its contents.

Once the drugs are packaged, they may be warehoused at a drug distribution center. When a health care provider requires drugs the drug distribution center delivers the low unit measure packages in accordance with the hospital's current needs. Once the low unit measure packages arrive at the hospital, the bar codes may be scanned by the hospital pharmacy to be automatically logged into the hospital's drug information management system in electronic communication with the drug distributor's management information system to track exactly what drugs and quantities arrived at the hospital in each shipment. Furthermore, the bar codes on the packages may be used to track the drugs that are placed in each drug dispensing machine at each patient care area within the hospital. The hospital's drug management information system will thus know the items placed in each drug dispensing machine in the hospital, including drug type, lot numbers, and expiration dates.

In addition, the present invention provides a computerized electronic interface between the hospital software system which tracks the drug distribution within the hospital and the drug distributor's software system at the drug distribution center warehouse. By enabling these two systems to communicate with each other, the system of the present invention provides a complete drug distribution management system from the warehouse to the patient care area within the hospital.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1A and 1B show a schematic diagram of a preferred embodiment of the system of the present invention;

FIG. 2 shows an actual size of a face of a plastic bag for low unit measure drug packaging of one embodiment of the system of the present invention;

FIG. 3A shows an actual size of a face of a drug packaging card for low unit dose drug packaging of another embodiment of packaging for the system of the present invention;

FIG. 3B shows an opposing side of the drug packaging card of FIG. 3A;

FIG. 4 shows an example of a preferred processing interface configuration of the computer software system of the present invention;

FIG. 5 shows an example of a data interface screen of a preferred form of the computer software system of the present invention;

FIG. 6 shows an example data screen of a preferred form of the computer software system of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENT(S)

Referring now to the drawings, and particularly FIG. 1A, a preferred embodiment of the system of the present invention is shown. The system shown at 10 may typically have at least three areas of data tracking of drug distribution. A first area 12 is the drug distribution center which is usually at a remote site from the health care provider institution. At the drug distribution center or at a computer facility in association with the drug distribution center, the first software program may be installed on a personal computer or network server for facilitating drug distribution management of low unit dose measures of the present invention.

A second drug distribution management software program of the present invention is installed at the health care provider facility 14 (for example in the pharmacy department) or at a computer facility in association with the health care provider. A third area for use of the present invention is at the various nursing stations 16 within the health care facility, primarily at drug dispensing machines 18 located at nursing stations.

In its preferred form, the present invention includes electronic communication and data sharing between the drug distribution software program and the health care provider software program, as well as between the drug dispensing machine software and the health care provider software program. The communication between the drug dispensing machines and the health care provider's pharmacy software program of the present invention, may be accomplished through hard wiring the drug dispensing machines throughout the facility to a central computer 20 operating the pharmacy second software program. Communication between the drug distribution center program of the present invention and the health care provider software program of the present invention may be accomplished via modem 22 and interface software running at each site as further described below. The interface may be, for example, a UNIX gateway. Since the distribution center may serve more than one health care provider in its region, each health care provider would be equipped to enter the distribution center computer system. This may involve having a gateway at the health care provider and another at the distribution center for gateway to gateway communication. Various other ways of setting up the communication link between the health care provider and the distribution center would be apparent to those of ordinary skill in the art when made aware of the contents of the present specification.

In accordance with a preferred embodiment of the present invention, several drug dispensing machines 18 within a health care facility 14 are in communication with the health care facility's central pharmacy computer ("CPC") 20 which is running the drug inventory management software program ("DIMS") of the present invention. Each drug dispensing machine ("DDM") may be uniquely identified by an identification code stored in the memory of the CPC. Each DDM may have a plurality of drawers, and pockets within each drawer, for storing certain drugs for later administering to patients. The DDM's identification code preferably includes information about the DDM's physical location within the health care facility.

The pharmacist may arrange to stock each DDM with particular drugs in particular drawers as well as in particular pockets within each drawer. Each DDM preferably includes data entry means such as a keypad to enable nursing staff to enter when a particular drug is administered to a patient, what drug was administered, what quantity was administered, and to which patient. Once entered into the DDM this information is automatically received by the CPC and utilized in DIMS running at the health care facility CPC.

Once the CPC receives the drug administering information from the plurality of DDM's, this information may be sent by the CPC to the drug distribution center computer ("DCC") also running a version of DIMS. It is important to note at this point that the DIMS running at the DCC and the DIMS running at the CPC may be the same program installed at multiple sites or it may be two separate programs adapted to communicate with each other. In either case, the CPC DIMS is adapted to track quantities and varieties of drugs received and administered to patients, and the DCC DIMS is adapted to track quantities and varieties of drugs shipped to particular health care providers and the remaining drugs those health care providers have purchased but which have not yet been requested for shipment to the health care facility. The DCC DIMS is also preferably adapted to produce an invoice to the health care provider for bulk drug purchases.

The software DIMS of the present invention is adapted to account for low unit dose measures of drugs. Unlike the drug distribution systems of old which accounted for bulk purchases but offered little or no low unit dose tracking, the present invention is especially designed to enable health care providers to reduce their own inventory of drugs and shift inventory management responsibilities to the drug distribution center. In this manner, the health care facility only receives those drugs that it will use in a relatively short period of time, thus substantially reducing inventory management responsibilities at the health care facility. Each health care facility would establish its own comfort level of drugs on hand and order from the drug distribution center accordingly. With the electronic communication between the DDM's and the CPC, the health care facility would have daily (or more frequently if desired) reports of drugs on hand at each DDM.

It should also be noted here that both the CPC and the DCC roles could be outsourced to third parties 24 in whole or in part, and still accomplish the intended purpose of the present invention. Furthermore, various programs may be written in various computer languages and formats to accomplish the roles of the CPC, DCC, and DDM data processors. Those specific programs and equipment described herein are not to be interpreted as limiting the broad scope of the present invention.

Another unique aspect of the present invention is the manner in which the low unit dose quantities of the drugs are packaged for delivery to each health care facility. In one embodiment of the present invention, a small plastic bag 30 is used as a package for unit dose measures of a drug. The individual doses of the drug may be contained in well known blister packs and placed in the plastic bag in predetermined quantities. The plastic bag may then be sealed with a perforated edge for later easy opening by health care providers. The plastic bags may be readily placed within the drawers of a DDM.

Prior to placing a drug in a plastic bag as described above, the bag may be printed on a face 32 thereof, with certain FDA required information. For example, the drug manufac-

turer's lot number **34**, the variety of the drug **36**, and the expiration date **38** of the drug may be printed or otherwise placed on the plastic bag. In addition, in a preferred embodiment of the present invention, certain of this information may be printed on the bag in the form of bar codes. With the use of bar codes there is less chance of human data entry errors when compared to manual data entry. Also, bar codes are faster to scan and thus enter into the DCC, CPC and DDM.

Using for example a low unit dose plastic package **30** in accordance with the present invention, containing a bar code **40** for expiration date of the drug, the system of the present invention offers a relatively fast system for tracking drugs that need to be removed from the DDM's. If a drug has expired, the CPC may inquire of the expiration dates of all of the drugs within a DDM (which in accordance with the present invention were earlier scanned and entered into the DDM). If expired drugs are shown to be present, the CPC will know exactly which DDM contains the expired drugs by referring to the DDM identification code. Thus, tracking of expired drugs for removal is handled electronically rather than manually checking each drawer of each DDM.

Likewise, lot numbers **42** and drug identification information **44**, as well as other information may be placed on the bag in bar code form. Bar code scanners **45** may be located at each site **12, 14**.

In another embodiment of the present invention a small paperboard card **50** serves as the drug packaging for low unit dose measures. The card is preferably of a size that enables it to be placed in a pocket of a drawer of a DDM. The card contains unit doses **51** of drugs in separate blister packs **52** attached to the card at perforated seams. The card may also contain bar coded information **54** as explained above.

In accordance with a preferred embodiment of the present invention, the CPC generates an electronic purchase order which is sent to the DCC. The purchase order contains a request for a bulk purchase of one or more varieties of drugs and also may include a request that only a certain lesser quantity than ordered be delivered at the present time. The DCC acknowledges the purchase order and fills the requested order. The DCC also tracks what quantities of the drugs ordered remain in inventory at the distribution center awaiting shipment upon request by the CPC. The DCC produces an invoice for the bulk order and sends the invoice to the CPC.

In a preferred embodiment, the distribution center ships the requested unit dose packages of drugs in "totes" (shipping containers) **60** which are predesignated for a particular DDM at the health care facility. Therefore, instead of the health care facility having to spend resources on getting the right drugs to the right DDM, the DCC can accomplish this in a much faster manner through its tracking of data received from the CPC (which received its data, in part, from each DDM) and the subsequent shipping of predesignated and properly labeled totes. The outside of each tote may also contain bar code information for easy tracking of totes as they are received at the health care facility.

The DIMS may be a Windows based program. The bar coding may be accomplished by commercially available bar coding equipment. The plastic bags and paperboard cards may be obtained from suppliers of similar packaging.

EXAMPLE CPC, DCC AND DDM SOFTWARE CONFIGURATION AND OPERATION STEPS FOR INTERFACING

1. Confirm that DDM system is set up with the CPC and in communication with the DCC. Within the DDM system, the interface may be configured with the following settings:

- a. Set to Stockless—ordering information is broken down at the item level per station.
- b. Set to Usage Net Vends—ordering quantities are based on the amount dispensed since the last time PO generated.
2. Match the DDM numbers used to identify items with the corresponding DCC item numbers.
3. Load either the DDM item numbers into the DCC or load the DCC item numbers into DDM.
- Steps
 1. Access the interface from the Import/Export option located off the utility menu in DCC.
 2. If more than one interface is installed, operator may need to click on the next or previous arrows in order to locate the DDM interface.
 3. Select the DDM interface as depicted below:
 4. Specify the location of the incoming files. To specify the drive and directory where the incoming file(s) resides, click the mouse on "Input Drive/Directory" and a screen will come up allowing operator to select a path. Or operator may type in the desired drive and directory. If operator does not specify an incoming path, the interface defaults to searching for incoming files in the DCC system directory. If none are found, the interface will terminate processing.
 5. "Input File Name" may be set to—*.850
 6. Save changes by clicking on the save button (disk icon).
 7. To configure the interface, click on the configuration button (wrench icon) and this brings up the following screen:

Purchase Order Items

This screen will be explained within the "Running the Interface" section of this guide. To continue with the setup and configuration, click the Processing Options tab.

Processing Options

Initially, fields set with default system settings.

1. Purchase Order Settings

PO Number—This is the purchase order number assigned to the incoming DDM order. The purchase order number may **12** alphanumeric characters.

Confirm PO Number—If selected, the following screen will be displayed before an order is created within the DCC system for each incoming DDM order. The screen displays the purchase order number that will be associated with the incoming DDM order.

Confirm whether or not operator wants to use this purchase order number. Operator may reset the number by typing in a new one and then select continue (rocket icon). The newly entered purchase order number is assigned to the incoming DDM order.

Increment PO Number—If selected, the purchase order number will automatically be incremented during processing. Once selected, specify the incremental value for the purchase orders.

Department—Enter the department code associated with the items on the incoming DDM order. This department code may be associated with all items on the order. Leave blank if operator does not want to assign a department code to the ordered items.

Ordering Options

Default Ordering Threshold—Percent of ordering unit met before item is ordered. This field sets the ordering level for all items. The ordering threshold must be met or

exceeded for an item to be ordered. For example, if the threshold is set at 80% for a 100 count bottle of Tylenol, the interface will not place an order until at least 80 tablets have been requested from the DDM system. The ordering threshold value may be stored in the UDF2 field within Item Maintenance.

Track Holdover Item Quantities—By activating this field, the interface will carry over the extra quantity of a particular item or the quantity of an item that did not meet the ordering threshold and use it when calculating the next purchase order quantity.

Continuing from the above example, say only 80 Tylenol tablets were requested from the DDM. However, the hospital was shipped a 100 count bottle. The hospital received twenty additional tablets. The interface will track the additional tablets, and when the next request for that particular Tylenol comes through, the interface will subtract the 20 tablets from the requested amount. It is this adjusted value that will be compared to the ordering threshold.

Another scenario where this setting comes into play occurs when the Tylenol order is for 20 tablets. This does not meet the ordering threshold, so the item is not ordered. These 20 tablets will carry over and be added to the next request for Tylenol.

If this field is not activated, the carry over quantities are not tracked and each request is evaluated on an individual basis. It is recommended to activate this option.

Round Up Order Quantities—Round calculations up to the next ordering unit. For example, if activated and an order for 135 Tylenol tablets comes across, the interface would order two 100 count bottles.

Narcotic Options

Select one option

Track Narcotics & Generate PO—The interface will generate a purchase order for narcotic items that are ordered by the DDM system. If selected, enter the Blank Number in the available space.

Track Narcotics & Manually Generate PO—The ordered quantities for narcotic items will be tracked within the interface, but a purchase order will not automatically be generated for these items. These items will be tracked until a purchase order for narcotic items is manually requested. There is a mechanism for generating this purchase order on the Purchase Order Items screen. The "Running the Interface" section offers manually triggering a purchase order for narcotic items.

Do Not Process Narcotic Items—All orders for narcotic items are ignored by the interfaces. Ordering narcotic items for the DDM system is handled outside this interface. To save changes click on the save button (disk icon). Continue with the setup and configuration by clicking the Report Option tab.

Report Options

Report Setting

Print Order Exception Report when processing order—If activated, the Order Exception Report will automatically be generated and printed, if appropriate, while the incoming DDM order is being processed. Continue with the setup and configuration by clicking the Setup Options tab.

Setup Options

I. Cross-Reference Method

Denote whether DCC item numbers are matched up and stored in the DDM alternate ID field for all items, or whether

the DDM item numbers are matched up with their corresponding DCC item numbers and stored within the DCC system.

If DDM item numbers are stored in DCC, the following will be displayed.

II. DDM Item # Found In

Identify in which field the DDM item numbers are stored within the DCC system. Both the "Stock Number" and the "UDF1" fields are accessible through Item Maintenance. At this point setup and configuration are complete, and the system is ready to import purchase orders from the DDM system.

Running the Interface

Steps:

1. The interface is run from the Import/Export option located off the utility menu in the DCC.

2. Select the DDM interface.

3. Adjust "Input Drive/Directory" as needed.

4. Save changes by clicking on the save button (disk icon).

5. To execute the interface, click on the launch button (rocket icon). The DDM order will be imported into the DCC. The interface will accumulate the item quantities across stations into one purchase order. If there are multiple purchase order files from the DDM, all items and order quantities will be consolidated into one purchase order within the DCC.

6. The interface will notify operator upon completion.

7. When processing has finished, review the incoming order within the Purchase Order section of DCC.

8. Also, there is a separate screen within the configuration portion of the interface for reviewing purchase order items and for tracking carry over quantities. This is accessed from the main DDM interface screen. To bring it up, click on the configuration button (wrench icon). The following screen appears:

Purchase Order Items

I. Item Grid

All items that have been ordered through the DDM system are listed. The main purpose of this grid is to allow review, and if necessary, adjustments to the carryover quantity and ordering threshold for a particular item.

Columns:

PO #*—the last purchase order that this item appeared on. If blank, the item was not ordered during the most recent processing or there is overstock of that particular item which keeps it from being reordered.

Item #*—DCC's item number for this product.

Description*—the trade name of the item as identified by the manufacturer.

Stock #*—the corresponding DDM item number for this product.

Class*—narcotic classification UOIF*—Unit Of Issue Factor—the number of units in the packaged product. Can be edited within Item Maintenance to reflect the number of unit doses contained within the package.

Track Qty—this is the carry over quantity associated with the item. A negative value represents overstock and that amount needs to be deducted before an order is placed. A positive value is the ordering quantity that has been accumulated to this point for the item. This value will be added to subsequent orders and compared against the ordering threshold. This column is highlighted because the value can be edited. Adjustments can be made to this field as deemed necessary.

Ord %—the ordering threshold associated with that particular item. This column is highlighted because the value can be edited. Adjustments can be made to this field as deemed necessary.

*—Fields can not be edited in normal browse mode. Only Item # and Stock # can be edited in ADD mode (plus icon).

II. Additional Features

Exception Override—there is capability to override an exception item status and order that item. In other words, if an item did not meet the ordering threshold, select that item and generate a purchase order for it.

Steps:

1. Tag the desired exception item(s). This can be accomplished two ways. One way is to select each item individually. Do this by marking the first column (*) with either the mouse or by hitting the space bar. The other manner for selecting exception items is to use the “Tag Exception Items for Order” option. Click the option button (check box icon). A list of options will appear. Select the “Tag Exception Items for Order” option and all exception items will be selected for the purchase order. Deselect an item by clicking on the selected check.

2. Select the launch button (rocket icon) to create a purchase order with the selected exception items.

3. Review the purchase order within DCC.

Adding Items—operator may add items individually to the table. Choose to do this if operator wants to preset the item with a unique threshold or tracking quantity.

Steps:

1. Click on the add button (plus icon) from the toolbar.
2. Fill in the appropriate data: DCC item number, stock number, track quantity, and threshold.

3. Click on the save button (disk icon) to save addition.

Narcotic Ordering—This feature is meant to be used in conjunction with the “Track Narcotics & Manually Generate PO” processing option. Order quantities have been tracked within the interface. When ready, operator may create a purchase order for the narcotic items.

Steps:

1. Tag the desired narcotic item(s). This can be accomplished two ways. One way is to select each item individually. Do this by marking the first column (*) with either the mouse or by hitting the space bar. The other manner for selecting exception items is to use the “Tag Narcotic Items for Order” option. Click the option button (check box icon). A list of options will appear. Select the “Tag Narcotic Items for Order” option and all narcotic items will be selected for the purchase order. Deselect an item by clicking on the selected check.

2. Select the launch button (rocket icon) to create a purchase order with the selected narcotic items.

3. Review the purchase order within DCC.

III. Screen Commands

Search—search for a specific item number, purchase order number, or stock number by typing in the desired number within the space provided. The area to enter the search values can be found above the command buttons.

Use the Tab key and/or the mouse to maneuver on the screen.

To exit the interface configuration, click on the exit button (exit door icon).

To delete an item record, click on the delete button (garbage can icon).

What is claimed is:

1. A system for drug distribution to health care providers, said system comprising:

a first drug inventory management software program for a drug distribution center;

a second drug inventory management software program for a health care provider facility computer;

a third drug inventory management software program for a nursing station, said third software program in association with a drug dispensing machine;

a low unit measure dose packaging including contents of a particular variety of drug, said packaging including at least one bar code whereby the information gathered from scanning said bar code is entered into said first and said second software programs; and

a first communication link between said first software program and said second software program and a second communication link between said second software program and said third software program, said first and second communication links adapted to enable drug inventory information at said nursing station within said health care provider to be shared with said drug distribution center to enable said drug distribution center to have knowledge of drug quantity and variety needs at said health care provider.

2. The system of claim 1, wherein said bar code includes information pertaining to a drug manufacturer's lot number from which the drugs within said package were obtained.

3. The system of claim 1, wherein said bar code includes information pertaining to an expiration date of the drugs contained within said packaging.

4. The system of claim 1, wherein said bar code includes information pertaining to the type of drug contained within said packaging.

5. The system of claim 1, wherein said packaging is a sealed plastic bag containing at least one unit dose measure of a drug.

6. The system of claim 1, wherein said packaging is a paperboard card including a plurality of unit dose measures of a drug in blister packs attached to said card.

7. The system of claim 1, further comprising:

a drug dispensing machine at said health care provider, adapted to receive said low unit measure package.

8. The system of claim 1, wherein said first drug inventory management software program tracks the total low unit measure quantities of drugs delivered to said health care provider and the balance of the quantity of drugs remaining from a bulk purchase of said drugs by said health care provider.

9. The system of claim 1, wherein said distribution center software is adapted to produce an invoice to said health care provider for a bulk purchase of said drugs.

10. The system of claim 1, wherein said first drug inventory management software program tracks drugs delivered to said health care provider, in low unit dose measurements.

11. The system of claim 10, wherein said first drug inventory management software program creates an invoice to said health care provider for drugs purchased in bulk.

12. The system of claim 1, wherein said drug distribution center maintains an inventory of drugs purchased by said health care provider and warehouses said purchased drugs at said drug distribution center while intermittently delivering purchased drugs to said health care provider in accordance with levels of need of said health care provider as indicated by said second drug inventory management software program.

11

13. A method for drug distribution to health care providers, said method comprising the steps of:

providing a first drug inventory management software program to be operated for a drug distribution center;

providing a second drug inventory management software program to be operated at a health care provider;

providing a third drug inventory management software program to be operated in association with a drug dispensing machine at said health care provider;

providing a low unit measure dose packaging including contents of a particular variety of drug, said packaging including a bar code indicating information about said contents;

scanning said bar code to thereby cause data from said bar code to enter at least one of said first program or said second program or said third program; and

providing a first communication link between said first software program and said second software program and a second communication link between said second software program and said third software program, said first and second communication links to enable drug inventory information at said drug dispensing machine within said health care provider to be shared with said drug distribution center to enable said drug distribution center to have knowledge of drug quantity and variety needs at said health care provider.

14. The method of claim 13, wherein said first software program and said second software program are the same program operating at at least two locations.

12

15. The method of claim 13, wherein said first software program and said second software program are separate and distinct programs operating at separate locations.

16. The method of claim 13, wherein said first software program and said second software program are part of one central software program, said central software program operating at at least one location and in electronic communication with said first and said second programs.

17. The method of claim 13, wherein said bar code contains information relative to an expiration date of said drug.

18. The method of claim 13, wherein said bar code contains information relative to a manufacturer's lot number of said drug.

19. The method of claim 13, further comprising:

placing an order through said second software program;

receiving said order at said first software program;

delivering a first portion of said order to said health care provider;

maintaining a second portion of said order at said distribution center.

20. The method of claim 19, further comprising:

tracking drug inventory levels purchased by said health care provider, with said first software program.

* * * * *

Pharmaceutical scam

Use audit to detect 'Pyramid Cube Scheme'

by Jerome Richard Gardner

EVERY HOSPITAL PURCHASING AGENT, buyer and material manager should be continually searching for and trying to obtain the best product at the best price.

Volume is one of the most common influential predictors of price. It is the key factor that contributes the most to the reduction of the price of a product. If a hospital has adequate short-term storage facilities and high turnover, it can order large quantities of goods and obtain volume discounts inherent in standardized volume procurement. Increased volume also establishes a greater usage base for future contract negotiations of price and represents a greater commission level for salespersons.

Volume purchase incentives have also been expressed clearly and reinforced by the government in the "prudent buyer principle" in Section 2103 of the *Medicare Provider Reimbursement Manual*. It says:

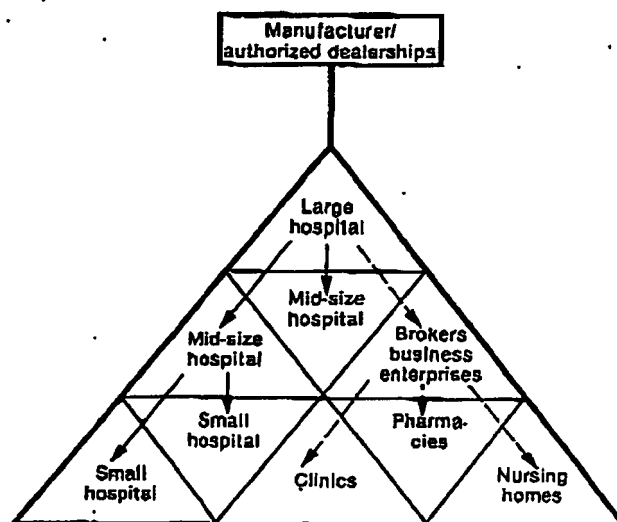
The prudent and cost-conscious buyer not only refuses to pay more than the going price for an item or service, he also seeks to economize by minimizing cost. This is especially so when the buyer as an institution or organization which makes bulk purchases can, therefore, often gain discounts because of the size of its purchases. It is quite common that discounts are given in these instances. In addition, bulk purchase of items or services often give leverage in bargaining with suppliers for other items or services. Any alert and cost-conscious buyer seeks such advantages, and it is expected that Medicare providers of services will also seek them.

Shared services agreements

Since the early 1900's tax-exempt hospitals have organized and participated in shared purchasing arrangements (shared services agreements). These arrangements were formed to obtain preferential prices for one's "own use" in compliance with the law. By combining their purchasing efforts, hospitals were able to increase their volume/usage base, and thereby strengthen their position in negotiating lower prices.

Continued on page 74

Exhibit 1: Comparison of shared services agreement with 'the Pyramid Cube Scheme'



Shared services agreement

- Legal — for one's "own use"
- Preferential prices
- Cost containment for hospital

Pyramid cube scheme

- Illegal
 - 501(c)(3) status jeopardy
 - Offset Medicare reimbursement problems
 - Violation of antitrust laws
- Discrimination in price (violation of U.S. Code Statutes)
- Profits to middleman
 - No warehousing costs
 - No insurance/handling costs
 - No inventory
 - No investment (cash outlay)

The term "Pyramid Cube Scheme" denotes the resaling ripple effect from large institutions (lowest cost/direct access) to local satellite clinics, small drugstores, and nursing homes.

Photograph: David Schart,
Scanning Electron Microscope
Carolina Jasmine Enlarged 95X

BEST AVAILABLE COPY



Computerized equipment finance comparisons can save you money.

Leveraged leasing can be one of the fastest and simplest ways to acquire capital equipment. It can be less expensive than even tax-exempt bond financing depending on the particular circumstances.

With Lease Investment Banking, LINC offers a fresh approach. Our computer model allows you to compare different equipment acquisition strategies side-by-side, using your own assumptions. You get the straight figures in black and white, with no confusion.

Then, if one of LINC's many programs does suit your needs, we can underwrite your acquisition on the spot. As lease investment bankers, we're able to bid firm, bid very competitively, and commit forward for a year or more if you wish. It all means less risk to you.

You may already have a favorite leasing company, but we think you should see what a lease investment banker can do for you. Contact us for a competitive quote. LINC's headquarters are in Three Illinois Center, 14th Floor, 303 East Wacker Drive, Chicago, Illinois 60601. Call Lease Investment Corporation at (312) 467-5500. Other offices are in Boston, Cleveland and Atlanta.

A Scientific Approach to Growth Through Lease Investment Banking.

Lease
Investment
Corporation

linc

For more facts circle 200 on reply card.

**See us at AHA
booth 4707**

Pyramid Cube Scheme

From page 72

Pyramid cube scheme

It appears that a new and questionable approach to cost containment for pharmaceutical purchases has arrived, which for the purposes of this article will be called the "Pyramid Cube Scheme." (See Exhibit 1) Today, hospital purchasing personnel are being approached by questionable brokers/business enterprises who try to convince them to over-order pharmaceuticals for the purpose of reselling the excess pharmaceuticals to them for a profit, thereby reducing the hospital's costs.

The pharmaceutical products selected by the brokers are normally only sold direct or via authorized dealerships to the hospital intended for its own use and not for resale purposes.

The excess pharmaceuticals, warehoused in the hospital, are then resold and delivered by the brokers to local satellite clinics and small drugstores at a profit to the hospital and the brokers. Although a profit margin is incorporated in the price, the small institutions/businesses are now able to purchase the goods at a lower cost than they would normally pay to the manufacturer or dealerships. The greater the volume ordered by the hospital, the lower the obtainable bid price—the greater the margin for profit.

Legal aspects and ramifications

Although the hospital is reducing the cost of its pharmaceutical goods, the possible disadvantages to the hospital are often overlooked or ignored by the parties involved. There are several legal aspects that should be considered. They include:

- Improper recording of transactions. Accounting for profits in the hospital records, financial balance sheet presentations and sales tax applications.
- Effects on an institution's tax-exempt (501) (c) (3) organizational status.
- Problem in properly offsetting Medicare reimbursement. This creates a thin line between the felony of Medicare-Medicaid fraud abuse and the practice of selling drugs to the retail market.
- Violation of U.S. Code Statutes. The statutes make it unlawful for a buyer to knowingly induce or receive a discrimination in price.
- Legal suit. To resell goods without the expressed approval of the manufacturer.
- Violation of antitrust laws for misuse of "preferential prices" allowed by the 1938 Non-Profit Institutions Act (Public Law 75-650-16 U.S.C. 13c). The purchase and purpose of supplies for one's "own use" was defined for hospitals by the Supreme Court in *Abbott Laboratories et al v. Portland Retail Druggist Association, Inc.* (1975) as:
 - Inpatients, emergency facility patients and outpatients for the personal use of the patients in treatment or consultation on the hospital's premises;
 - Inpatients, emergency facility patients and out-

patients for the personal use of the patients for a limited and reasonable time away from the premises as a continuation of or supplement to the treatment at the hospital's premises (but not refills of former patients' prescriptions);

—Employees, members of physician staff, students working at the hospital and similar persons who are rendering services in connection with the hospital's activities—for their own use and the use of their dependents; and

—Occasional "walk-in" buyers in particular emergency situations where no other pharmacy is available.

Other ramifications

- Costs of warehousing. Cash flow effects.
- Security problems. Keeping non-employees out of storeroom areas.
- Potential for the mishandling of funds (kick-backs).

This article is intended to encourage hospitals to double check their internal procedures to ascertain if this practice is occurring. It can be checked using the audit process.

Audit checks to consider:

- Verify that appropriate accounting entries are made to reflect the responsibility for asset custody.
 - Scrutinize credits applied to pharmacy inventory, expense accounts.
 - Examine the origin of non-operating or other operating revenue account entries.
- Verify accounts payable records.
 - Review purchase orders, invoices, receiving reports to ascertain proper/authorized execution. Inspect orders for high-lighted segregation notations, lack of documentation, address changes, or shipments to a location other than the hospital.
- Verify that appropriate segregation of functional responsibilities are adequate for provisions for independent verification.
 - Analyze organizational chart, work flow in departments, job descriptions, and the quality of personnel hiring practices.

These tactical measures provide assurance that transactions are properly authorized and accurately recorded.

Remember the appropriate and careful control scrutinization of pharmacy inventory is very important to both the provider and recipient of hospital services. Through proper and acceptable measures hospitals can control and maintain their pharmacy inventories at levels that will insure adequate stock to meet the needs of their patients and at the same time minimize their costs.

A shared purchasing agreement, used legally to obtain preferential prices for goods for one's "own use," is an acceptable approach to cost containment. The "Pyramid Cube Scheme," used as an illegal profit for others, should be discouraged, especially for all tax-exempt hospitals. □



US005890129A

United States Patent [19]

Spurgeon

[11] **Patent Number:** **5,890,129**
[45] **Date of Patent:** **Mar. 30, 1999**

[54] **SYSTEM FOR EXCHANGING HEALTH CARE INSURANCE INFORMATION**

[76] **Inventor:** **Loren J. Spurgeon**, 521 16th Ave.
West, Kirkland, Wash. 98033

[21] **Appl. No.:** **865,719**

[22] **Filed:** **May 30, 1997**

[51] **Int. Cl.⁶** **B42D 1/10**

[52] **U.S. Cl.** **705/4; 705/2; 705/3; 395/200.32;**
395/200.47; 707/1; 707/10; 707/102

[58] **Field of Search** **705/2, 3, 4; 395/200.32,**
395/200.47, 200.33; 707/1, 10, 102, 200

[56] **References Cited**

U.S. PATENT DOCUMENTS

5,664,109 9/1997 Johnson et al. 705/2

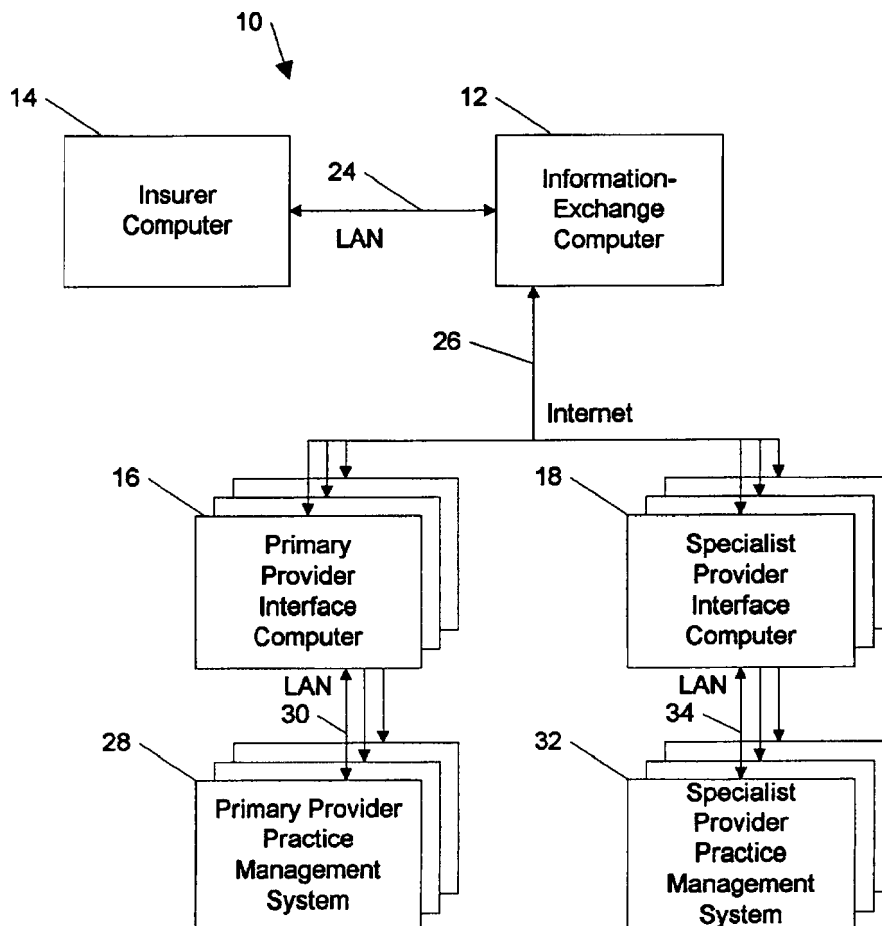
Primary Examiner—Thomas R. Peeso

Attorney, Agent, or Firm—Kolisch, Hartwell, Dickinson,
McCormack & Heuser

[57] **ABSTRACT**

An information-exchange system is provided for controlling the exchange of business and clinical information between an insurer and multiple health care providers. The system includes an information-exchange computer that is connected over a local area network to an insurer computer using a proprietary database and over the Internet to health-care provider computers using open database-compliant databases. The information-exchange computer receives subscriber insurance data from the insurance computer database, translates the insurance data into an exchange database, and pushes the subscriber insurance data out over the Internet to the computer operated by the health-care provider assigned to each subscriber. The information-exchange system stores the data in the provider database. The information-exchange system also provides for the preparation, submission, processing, and payment of claims over the local area network and with push technology over the Internet. In addition, prior authorization requests may be initiated in the provider computers and exchanged over the information-exchange system for review by the insurer computer. Processed reviews are transmitted back to the provider computer and to a specialist computer, if required, using push technology over the Internet.

24 Claims, 16 Drawing Sheets



EXHIBIT

tabbies

C

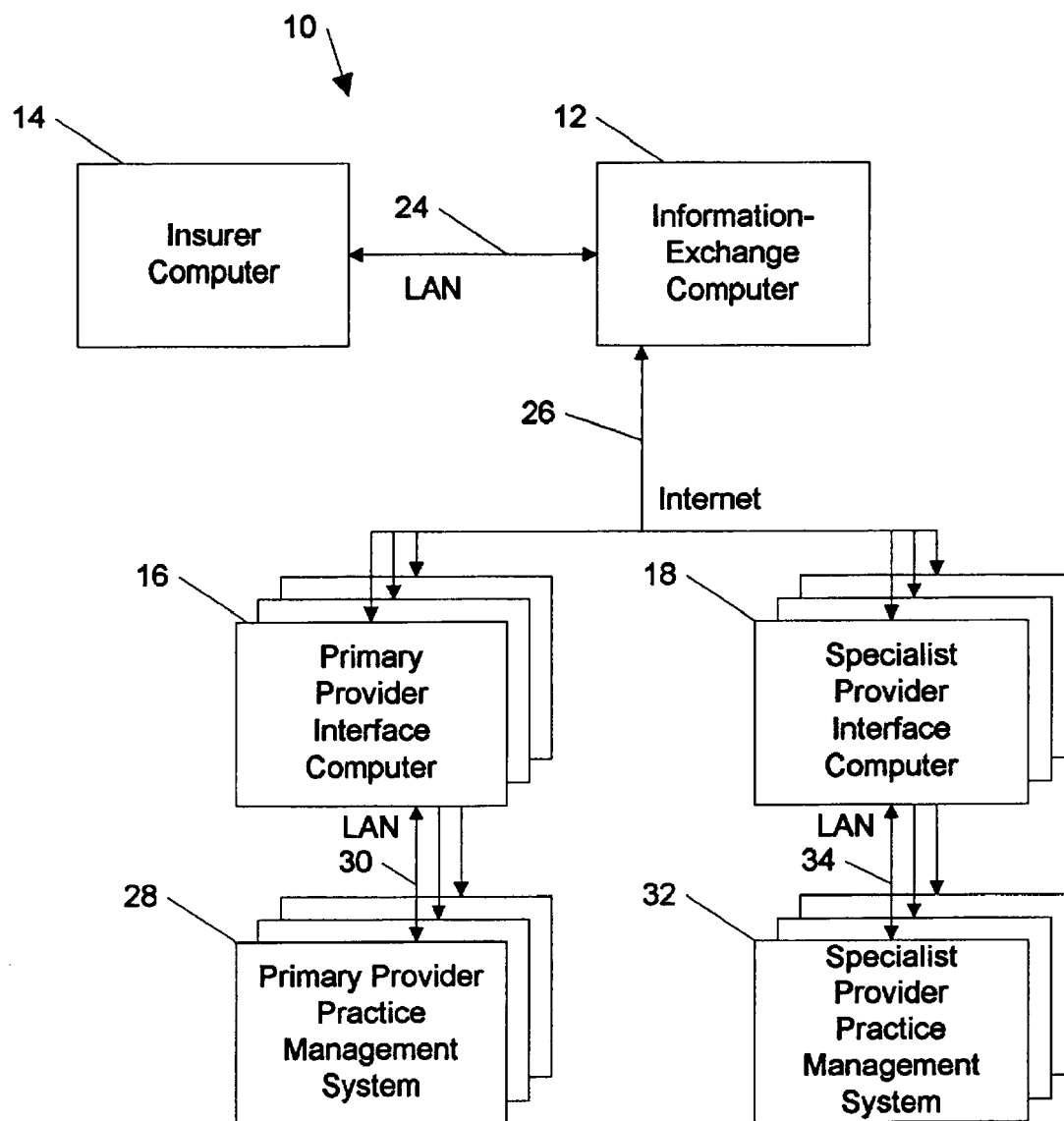


Fig. 1

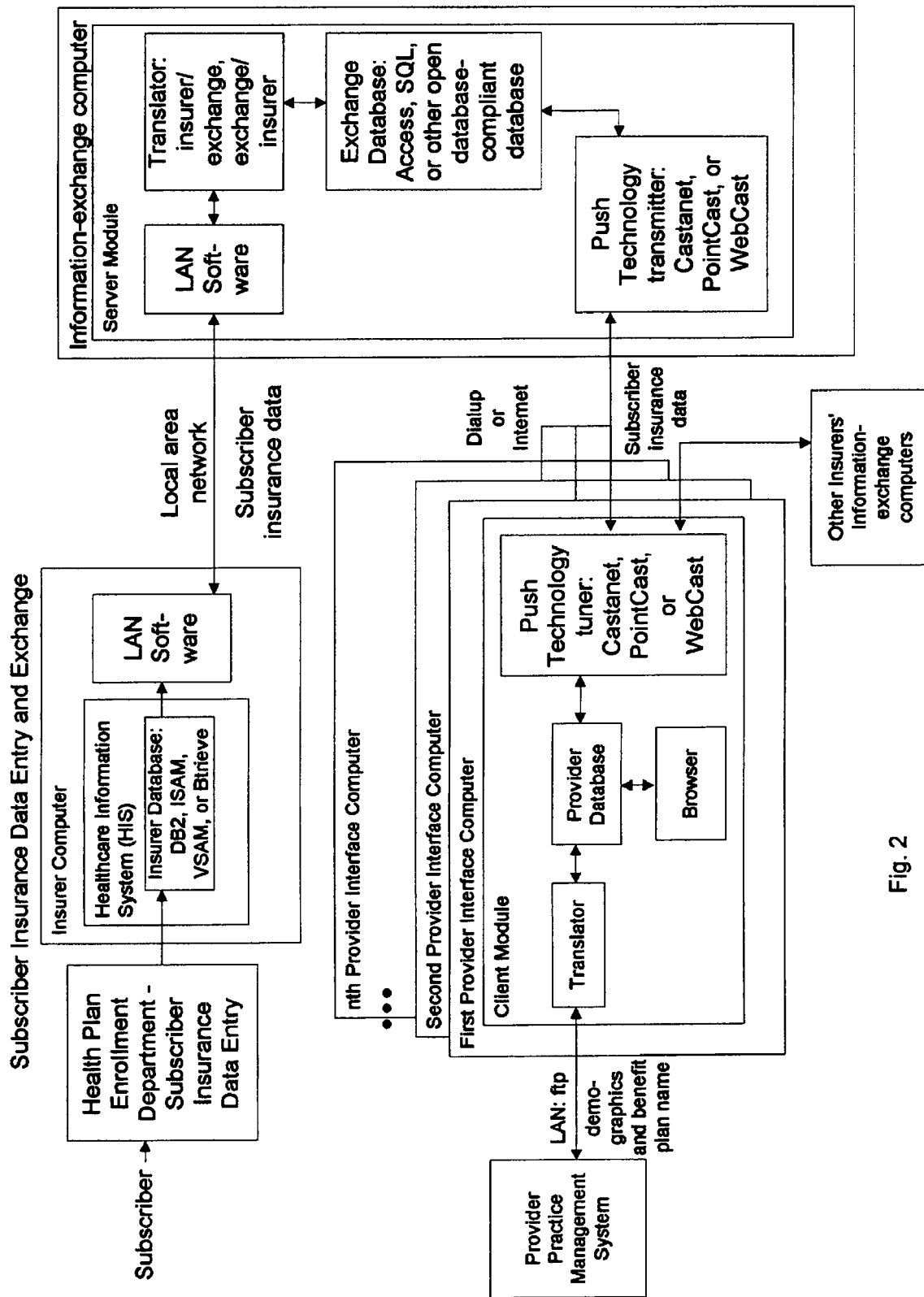


Fig. 2

Preparation, Submission, Processing, and Payment of Claims

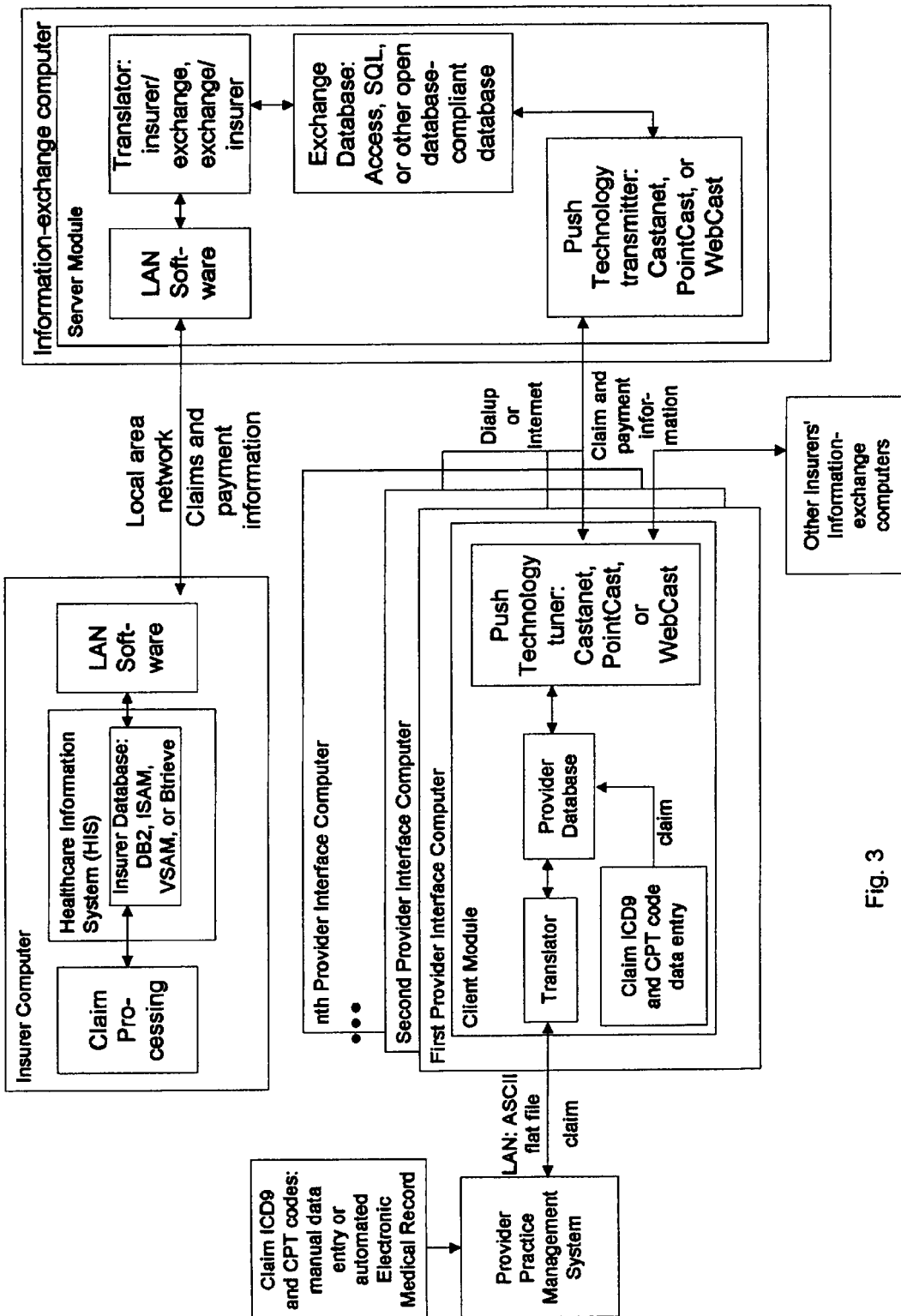


Fig. 3

Prior Authorization Requests, Exchange, and Review

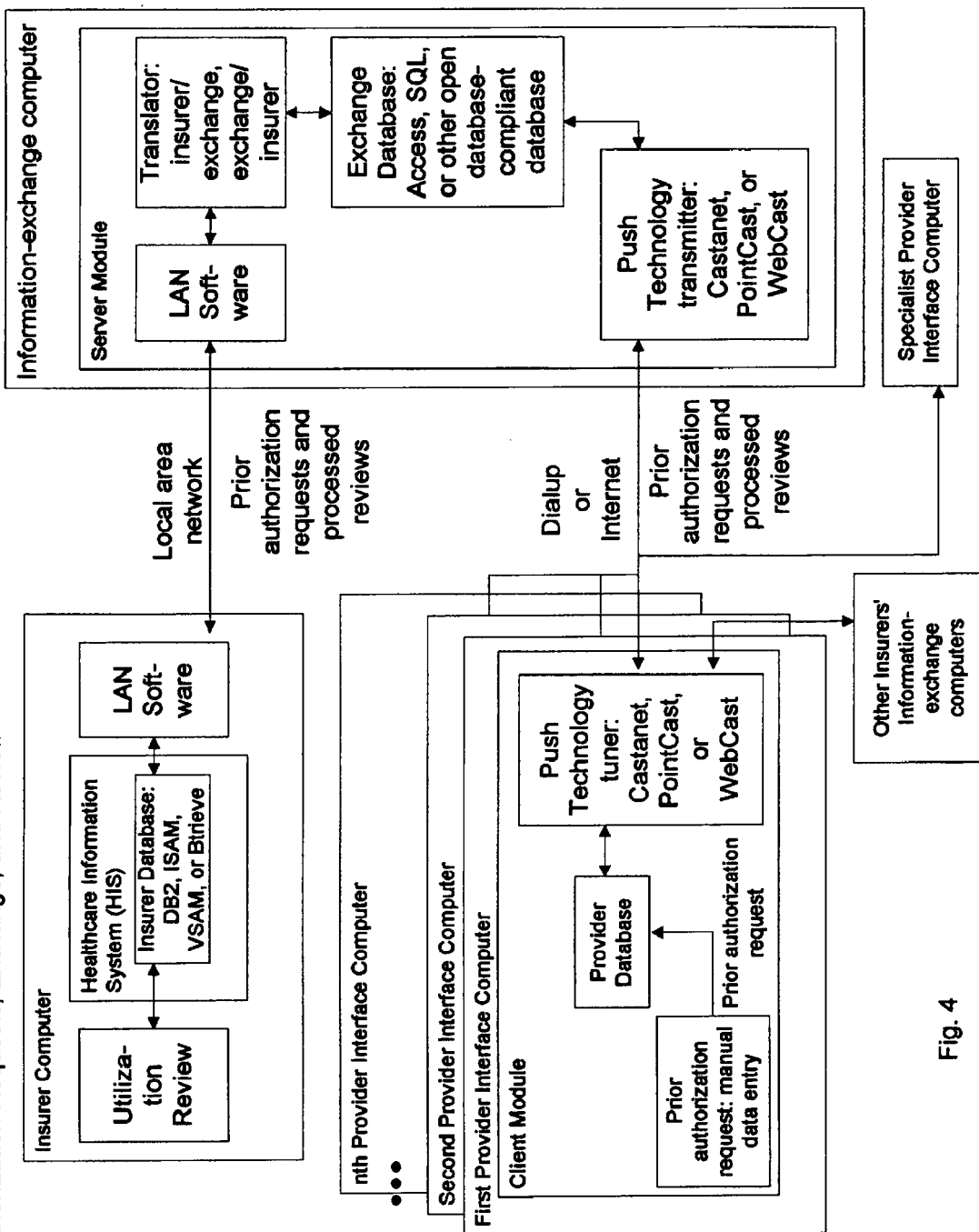


Fig. 4

Member Demographics
Information

MEMBER

<input type="text"/>	<input type="text"/>				
Member Number	SSN (if different)				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Member-Last Name	First	M. I.	Age	Sex	DOB
<input type="text"/>					
Home Address					
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
Home Address-Line 2	City	ST	Zip		
<input type="text"/>	<input type="text"/>				
Home Telephone	Work Telephone				

EMPLOYER

<input type="text"/>	<input type="text"/>			<input type="text"/>	<input type="text"/>
Employer Name					
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
Employer Address	City	ST	Zip		
<input type="text"/>	<input type="text"/>	<input type="text"/>			
Employer Phone Number	Group Number	Plan Number			

DEPENDENTS

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Dependent 1-Last Name	First	MI	Age	Sex	DOB
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Dependent 2-Last Name	First	MI	Age	Sex	DOB
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Dependent 3-Last Name	First	MI	Age	Sex	DOB
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Dependent 4-Last Name	First	MI	Age	Sex	DOB
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Dependent 5-Last Name	First	MI	Age	Sex	DOB
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Dependent 6-Last Name	First	MI	Age	Sex	DOB

Fig. 5

Benefit Package Information

Member Number

Member Name

Patient Name

Patient SSN

BENEFIT DESCRIPTION**CO-PAY**

PCP Office Visit	\$ 10.00
Specialist Office Visit	\$ 0.00
Prescription Drugs	\$ 5.00
Inpt Room and Board	\$100.00
Inpt Mental Health	\$ 30.00
Opt Mental Health	\$ 15.00
Inpt Substance Abuse	\$ 30.00
Opt Substance Abuse	\$ 15.00
Hosp Emergency Room	\$ 35.00
Urgent Care Center	\$ 10.00
Home Health/Hospice/RN	\$ 10.00
Spinal Benefit	\$ 10.00

Fig. 6

Eligibility Information

Member Number

Member Name

Patient Name

Patient SSN

ELIGIBILITY INFORMATION

Employer

Group Number

Eligibility Type

Effective Date

Expiration Date

Employer

Group Number

Eligibility Type

Effective Date

Expiration Date

Employer

Group Number

Eligibility Type

Effective Date

Expiration Date

Notes

Fig. 7

Primary Care Physician (PCP) Assignment

Member Number
Member Name
Patient Name
Patient SSN

PCP ASSIGNMENT

PCP Assigned
Specialty
Provider Number
EIN Number

Location 1

Group Name
Group Provider Number
Group EIN Number
Address
City
ST
Zip
Telephone
FAX

Location 2

Group Name
Group Provider Number
Group EIN Number
Address
City
ST
Zip
Telephone
FAX

Location 3

Group Name
Group Provider Number
Group EIN Number
Address
City
ST
Zip
Telephone
FAX

Fig. 8

Claim Submission

PLEASE
DO NOT
STAPLE
IN THIS
AREA

APPROVED OMB-0935-0008

HEALTH INSURANCE CLAIM FORM														
PICA <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>														
1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> CHAMPUS <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GHP HEALTH PLAN <input type="checkbox"/> FECA BLK LUNG <input type="checkbox"/> OTHER <input type="checkbox"/>					1a. INSURED'S ID NUMBER (FOR PROGRAM IN ITEM 1)									
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)					3. PATIENT'S BIRTH DATE SEX M <input type="checkbox"/> F <input type="checkbox"/>					4. INSURED'S NAME (Last Name, First Name, Middle Initial)				
5. PATIENT'S ADDRESS (No., Street) CITY STATE ZIP CODE TELEPHONE (Include Area Code)					6. PATIENT'S RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/> 7. PATIENT STATUS Single <input type="checkbox"/> Married <input type="checkbox"/> Other <input type="checkbox"/> Employed <input type="checkbox"/> Full-Time <input type="checkbox"/> Part-Time <input type="checkbox"/> Student <input type="checkbox"/>					7. INSURED'S ADDRESS (No., Street) CITY STATE ZIP CODE TELEPHONE (Include Area Code)				
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)					10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (CURRENT OR PREVIOUS) YES <input type="checkbox"/> NO <input type="checkbox"/> b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>					11. INSURED'S POLICY GROUP OR FECA NUMBER				
a. OTHER INSURED'S POLICY OR GROUP NUMBER					a. INSURED'S DATE OF BIRTH SEX M <input type="checkbox"/> F <input type="checkbox"/>					b. EMPLOYER'S NAME OR SCHOOL NAME				
b. OTHER INSURED'S DATE OF BIRTH SEX M <input type="checkbox"/> F <input type="checkbox"/>					c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>					c. INSURANCE PLAN NAME OR PROGRAM NAME				
c. EMPLOYER'S NAME OR SCHOOL NAME					10d. RESERVED FOR LOCAL USE					d. IS THERE ANOTHER HEALTH PLAN BENEFIT? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, return to end complete item 9 a-d.				
d. INSURANCE PLAN NAME OR PROGRAM NAME					12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below. SIGNED _____ DATE _____					13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize payment of medical benefits to the undersigned physician or supplier for services described below. SIGNED _____				
14. DATE OF CURRENT: ILLNESS (First Symptom) or INJURY (Accident) or PREGNANCY (LMP)					15. IF PATIENT HAS HAD SAME OR SIMILAR ILLNESS, GIVE FIRST DATE					16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM _____ TO _____				
17. NAME OF REFERRING PHYSICIAN OR OTHER SOURCE					17a. ID # OF REFERRING PHYSICIAN					18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM _____ TO _____				
19. RESERVED FOR LOCAL USE					20. OUTSIDE LAB? YES <input type="checkbox"/> NO <input type="checkbox"/> CHARGES					21. MEDICAD RE submission CODE ORIGINAL REF. NO				
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. (RELATE ITEMS 1, 2, 3 OR 4 TO ITEM 24E BY LINE) 1. 3. 2. 4.					22. PRIOR AUTHORIZATION NUMBER					23. RESERVED FOR LOCAL USE				
24. A DATE(S) OF SERVICE FROM (MM/DD/YYYY) TO (MM/DD/YYYY)					B Place of Service C Type of Service D PROCEDURES, SERVICES, OR SUPPLIES (Specify Unusual Circumstances) E DIAGNOSIS CODE					F CHARGES G H I J K RESERVED FOR LOCAL USE				
25. FEDERAL TAX ID. NUMBER SSN <input type="checkbox"/> EIN <input type="checkbox"/>					26. PATIENT ACCOUNT #					27. ACCEPT ASSIGNMENT? (For gen. claims, see back) YES <input type="checkbox"/> NO <input type="checkbox"/>				
28. TOTAL CHARGE					29. AMOUNT PAID					30. BALANCE DUE				
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part hereof.) SIGNED _____ DATE _____					32. NAME AND ADDRESS OF FACILITY WHERE SERVICES WERE RENDERED (If other than home or office) Name Address City, State Zip Code					33. PHYSICIAN'S, SUPPLIER'S BILLING NAME, ADDRESS, ZIP CODE & PHONE # Name Address City, State Zip Code Phone				

(APPROVED BY AMA COUNCIL ON MEDICAL SERVICE 6/98)

PLEASE PRINT OR TYPE

FORM HCFA-1500 (12/90)
FORM OWCP-1500 FORM RRB-1500

Fig. 9

Prior Authorization Information

Demographics
Benefits
Provider
Referred To
Codes
Services
Sending To

Demographics

from

Member
Demographics
Screen

Fig. 10

Prior Authorization Information

Demographics

Benefits

Provider

Referred To

Codes

Services

Sending To

Benefits

from

**Benefit
Package
Screen**

Fig. 11

Prior Authorization Information

Demographics
Benefits
Provider
Referred To
Codes
Services
Sending To

**Provider
Information**

from the

**Provider
Database
in the
Marimba
Application**

Fig. 12

Prior Authorization Information

Demographics
Benefits
Provider
Referred To
Codes
Services
Sending To

**Referred To
Information**

from the

**Health Plan
Provider
Network
Database
(Chosen from a
Search Screen)**

Fig. 13

Prior Authorization Information

	Codes	
Demographics	ICD9	Description
Benefits	<input type="text"/>	<input type="text"/>
Provider		
Referred To		
Codes	<input type="text"/>	<input type="text"/>
Services		
Sending To		
	CPT	Description
	<input type="text"/>	<input type="text"/>
	<input type="text"/>	<input type="text"/>
	HCPCs	Description
	<input type="text"/>	<input type="text"/>
	<input type="text"/>	<input type="text"/>

Fig. 14

Prior Authorization Information

Demographics	<div><h3>Services and Dates</h3><p>DATES</p><table><tr><td>Onset</td><td>Encounter</td><td>Service</td></tr><tr><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td></tr><tr><td>Admission</td><td>Procedure</td><td></td></tr><tr><td><input type="text"/></td><td><input type="text"/></td><td></td></tr><tr><td colspan="3">Days or Visits</td></tr><tr><td>Requested</td><td>Approved</td><td>Actual</td></tr><tr><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td></tr><tr><td colspan="3">Place of Service</td></tr><tr><td colspan="3"><input type="text"/></td></tr><tr><td colspan="3">Type of Admission</td></tr><tr><td colspan="3"><input type="text"/></td></tr></table></div>	Onset	Encounter	Service	<input type="text"/>	<input type="text"/>	<input type="text"/>	Admission	Procedure		<input type="text"/>	<input type="text"/>		Days or Visits			Requested	Approved	Actual	<input type="text"/>	<input type="text"/>	<input type="text"/>	Place of Service			<input type="text"/>			Type of Admission			<input type="text"/>		
Onset		Encounter	Service																															
<input type="text"/>		<input type="text"/>	<input type="text"/>																															
Admission		Procedure																																
<input type="text"/>		<input type="text"/>																																
Days or Visits																																		
Requested	Approved	Actual																																
<input type="text"/>	<input type="text"/>	<input type="text"/>																																
Place of Service																																		
<input type="text"/>																																		
Type of Admission																																		
<input type="text"/>																																		
Benefits																																		
Provider																																		
Referred To																																		
Codes																																		
Services																																		
Sending To																																		

Fig. 15

Prior Authorization Information

Demographics

Benefits

Provider

Referred To

Codes

Services

Sending To

Sending To

Department

Fig. 16

SYSTEM FOR EXCHANGING HEALTH CARE INSURANCE INFORMATION

FIELD OF THE INVENTION

The present invention relates generally to a computerized system that controls the exchange of business and clinical information necessary for efficient administration of services in a health care delivery system. More specifically, it concerns a computerized system for controlling the exchange of subscriber demographics, benefit plan, eligibility, prior authorization, claims, quality assurance and governmental regulatory information between an insurance company and multiple health care provider groups.

BACKGROUND

Costs of health care in the U.S. and elsewhere have been increasing dramatically in recent years, at least in part due to advances in medical technology which call for more expensive surgery and treatment regimes and complex diagnostic and therapeutic procedures. To control these escalating costs, insurers have developed a managed care model for health care insurance wherein the insurers' subscribers, i.e., health care consumers, pay a lower insurance premium in exchange for the insurers' assuming a greater degree of control over the provision of health care.

In the managed care model, insurers negotiate fee schedules with medical service providers. Furthermore, each insurer checks the credentials of health care providers before approving them to provide service under the insurer's health plan. The group of credentialed providers is referred to as a Network or Panel and may consist of hundreds of providers. As used herein, provider refers to a doctor or other health care provider, or groups thereof practicing together as a business entity. Each provider may belong to several Networks so that the provider can accept patients who subscribe to various insurance plans.

The insurers may additionally or alternatively manage care by paying a greater portion of the claim when the subscriber uses a preferred provider, or by requiring the subscriber to initiate care at the subscriber's primary care physician. After providing health services, the primary care provider or preferred provider submits a claim to the insurer.

When a primary care provider or preferred provider recommends surgery or special treatment outside the scope of services available at its office, the insurer, in a managed care system, requires that advance authorization be obtained through a process known as prior authorization or pre-certification. Prior authorization may also be required for some services provided by the primary care provider. If the proper authorization is not obtained beforehand, the insurer may deny coverage. The insurer may deny a claim for past treatment or a prior authorization for future treatment when the treatment is beyond the insurance coverage of the subscriber or not medically appropriate for the subscriber. Thus, under managed care, the insurer must carefully monitor the course of treatment recommended by the providers.

In operation, the managed care model requires constant exchange of large amounts of information between insurers and providers because the insurer tracks each subscriber's benefit plan, symptoms, diagnoses, treatment and other information to determine if the claims made by health care providers are covered and conform to actuarial guidelines of medically appropriate treatment regimens. Confusion and delay in the processing of such information are frustrating to all parties involved—treatment is delayed to subscribers; payments are delayed to providers; and dissatisfied subscri-

ers complain to their insurers and/or cancel their coverage. Ultimately, dissatisfied providers may opt out of the insurer's Network.

The potential for confusion and delay is heightened by the present limitations on the exchange of the information. In particular, each organization has a computerized system handling the particular requirements of the organization, but, unfortunately, these systems are not directly compatible. A subscriber enrolls in a health insurance plan, typically through the subscriber's employer, by providing demographic information to the health plan. These demographics, or enrollment data, are keyed into the insurer's computer system software application, referred to as a Healthcare Information System (HIS), and are then associated with a benefits package, eligibility information and Primary Care Provider (PCP) assignment. When the subscriber goes to a provider's office seeking health care, the subscriber must again provide the demographics to the provider who checks, by telephone or fax, the records of the insurer to verify eligibility. The provider manually enters these same demographics into their computer system, often referred to as a Practice Management System (PMS) application, consuming time and money and risking data-entry error. Another bottleneck in the exchange of information occurs when the provider determines that special treatment is required that must be pre-authorized pursuant to a utilization review. The provider prepares the prior authorization request and sends it to the insurer or a third party review agency by telephone, mail or fax. The insurer returns prior authorization approval or denial by the same inefficient, error-prone route.

The HIS system typically includes large, complex software applications costing from \$300,000 to \$1,000,000 and utilizes a proprietary database running on a midrange computer system such as IBM's AS/400. The providers typically use one of numerous, mutually incompatible PMS applications, many of which run on outdated Unix systems, although some are PC-based. Generally, each insurer's HIS is unique to that insurer and of the numerous PMS applications available, no single product has a significant market share. Each insurer deals with hundreds of providers and each provider deals with perhaps dozens of insurers. The differing operating systems and database structures within the applications prevent the direct transfer of information therebetween. The insurers and providers, each with their own separate island of information, are required to enter manually the same information repeatedly as the subscriber's case navigates among the islands of enrollment, care provision, prior authorization, claims, etc.

It is likely that these islands of information will persist despite the overall cost to the organizations as a whole because of each insurer's investment in their proprietary HIS software and databases and the competitive and non-standardized nature of the market for PMS applications. There are some integrated insurance and medical organizations which bring the islands of information under a one-world model where the insurer and all the providers work for one company and use common standardized data sets in all of their applications. This model, while potentially offering improved efficiency, is inadequate for two reasons. First, the subscribers still frequently require medical care outside the integrated companies either due to an emergency or specialized care that the benefits package covers. Second, this system is of no help to the many separate insurance and medical companies, which will persist for the foreseeable future in the free market. A need therefore exists for a system that allows the insurers and providers to continue to use their existing applications and, at the same time, reap the benefits of automatic exchange of insurance information.

SUMMARY OF INVENTION

The present invention is a system of exchanging clinical and business information, within the existing environment of disparate hardware and software, in a standard format over a standard transmission medium. The hub of the system is an exchange database located on a computer which will be referred to as a web server or information-exchange computer. The invented information-exchange system includes the information-exchange computer, as well as software applications that run on the web server and other "client" computers located at the providers' and the insurers' offices. The information-exchange system relies on the Internet, or direct dial up access, and Local Area Networks (LANs) to transmit information which the system has translated and reformatted. The information may be translated at the client or at the information-exchange computer, into a standard format.

The present invention is probably most easily understood by reference to an example of the system operation. Initially, the subscriber purchases insurance coverage from an insurer. The subscriber provides data to the insurer including eligibility dates and demographic information, e.g., name, address, employer and dependents, and selects a primary care provider. The insurer enters the demographic and eligibility data into the insurer's preexisting HIS software application and database and assigns a benefit package. The subscriber insurance data is imported over a LAN connection into the database on the web server. The subscriber insurance data is then transmitted to the primary care provider's PC over the Internet, or dial up access, using push technology that automatically broadcasts the data to the PC without further human intervention. At the provider's PC, the provider may view the transmitted information using an appropriate "client" software package, such as a browser. A provider interface portion of the information-exchange system running on the provider's PC also translates and reformats the information for the provider's specific PMS application and transmits it over a LAN to the computer running the PMS application.

The information-exchange system eliminates the need for manual reentry of subscriber insurance data at the provider's office. With the information-exchange system, the subscriber need only show an insurance card to the provider who can then immediately check the enrollment, benefit plan and eligibility information already resident in the information-exchange system and in the provider's PMS application.

After providing health care services to the subscriber, the provider normally processes a claim using its PMS application. The claim is then transmitted to the provider's information-exchange interface computer where a client application, i.e., a provider interface portion, of the information-exchange system translates and reformats the claim. For the providers who do not have a legacy PMS application, i.e., a PMS application in which the provider has invested money and employee training that the provider does not wish to write-off, the provider interface portion allows the direct entry of claim information at the provider's office. The provider interface portion then transmits the claim up to the web server and there it is translated, reformatted and transmitted via push technology to the insurer's HIS or to a third party claim processor. This automatic exchange replaces the prior system of the providers' printing out the claims and mailing or faxing the printed claims to the insurer for manual reentry.

If the primary care provider determines that treatment by a specialist or exceptional treatment by the provider is

indicated for the subscriber, a prior authorization request is submitted, in order to request a utilization review of the proposed treatment. The insurer previously would receive the requests by telephone, mail or fax. Using the provider interface portion of the information-exchange system, the provider enters information necessary for a prior authorization on the provider interface computer. The information-exchange system transmits, via push technology, the information up to the web server, which transmits the information to the insurer and/or to a third party review agency. In the course of this transmission, the information-exchange system translates and reformats the information as required for the receiving utilization review software, which may be running on the insurer's or third party review agency's computer. The utilization review software processes the prior authorization request to aid the insurer or third party review agency in determining the subscriber eligibility and the medical appropriateness of the prior authorization request.

When the insurer or the third party review agency completes the processing of the information, the information-exchange system receives the authorized or denied request and translates and reformats this data for the exchange database. If the request is approved for specialist treatment, the information-exchange system then transmits the review to a specialist provider interface computer at the specialist's office which translates and reformats the reviews for the specialist's PMS. The reviews, both approved and disapproved, are also transmitted to the original health care provider.

When integrating computers that use mutually incompatible databases, the information-exchange system can be visualized as a hub-and-spoke system with the information-exchange computer forming the hub. Spokes of the system extend out from the hub along the Internet, dial up access, or LANs to PC's and mid-sized computers operated by providers and insurers. Each spoke provides for the translating, reformatting, transmission and receipt of the information contained in the provider's or insurer's specific database. The information-exchange system may also include direct communications between provider interface computers and insurer computers when the databases are directly compatible.

A main advantage of the information-exchange system is the increased speed with which claims are processed and paid and with which a subscriber may learn if a requested treatment will be paid for by the insurer. The replacement of fax, telephone and mail with a high-speed, computerized system as a continuous conduit for all aspects of these requests produces the increased speed.

Opportunities for errors and miscommunications are also eliminated by the information-exchange system of the present invention. Updates are made directly, accurately and automatically by the software used by the insurers and providers without a requirement for manual reentry of information.

Another advantage of the present invention is that the provider need not be concerned with what HIS is used by the insurer, and the insurer is likewise unconcerned with the PMS of the provider. The providers and insurers can transmit clinical and business information back and forth automatically without having to translate directly between the incompatible databases. The information-exchange system provides for a common language for all while still permitting each to use the proprietary system of their choice.

These and other objects and advantages of the invention will be more fully understood by reference to the accompanying drawings and the detailed description to follow.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a system diagram of the information-exchange system showing the interconnection of the computers in the system.

FIG. 2 is a system flow diagram of the information-exchange system showing processing and exchange of subscriber insurance data.

FIG. 3 is a system flow diagram of the information-exchange system showing processing and exchange of a claim.

FIG. 4 is a system flow diagram of the information-exchange system showing processing and exchange of a prior authorization request and review.

FIG. 5 is a data screen provided by the information-exchange system for entry or review of subscriber demographics.

FIG. 6 is a data screen provided by the information-exchange system for entry or review of benefit package information.

FIG. 7 is a data screen provided by the information-exchange system for entry or review of eligibility information.

FIG. 8 is a data screen provided by the information-exchange system for entry or review of primary care physician assignment.

FIG. 9 is a data entry screen provided by the information-exchange system for entry and submission of claims.

FIG. 10 is a data screen provided by the information-exchange system for entry or review of subscriber demographics during prior authorization entry.

FIG. 11 is a data screen provided by the information-exchange system for entry or review of benefits package during prior authorization entry.

FIG. 12 is a data screen provided by the information-exchange system for entry or review of provider information during prior authorization entry.

FIG. 13 is a data screen provided by the information-exchange system for entry or review of referred-to information during prior authorization entry.

FIG. 14 is a data screen provided by the information-exchange system for entry or review of codes information during prior authorization entry.

FIG. 15 is a data screen provided by the information-exchange system for entry or review of services and dates information during prior authorization entry.

FIG. 16 is a data screen provided by the information-exchange system for entry or review of sending-to information during prior authorization entry.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention is an information-exchange system, shown generally at 10 in FIG. 1, which provides for the processing of health-insurance data over local area networks, the Internet, through dial up access, satellite uplink or any other network using an open communications protocol, such as TCP/IP. The system includes an information-exchange computer 12, also referred to as a web server, local information-exchange software operable on that computer, and, in some cases, remote information-exchange software operable on client computers. The invented system integrates the operation of the client computers which include insurer computers 14, primary health

care provider interface computers 16 and specialist health care provider computers 18. The insurer computer may be replaced by third party computers which provide for claims processing and review of prior authorization requests. The insurer computer or the third party computer and the information-exchange computer are preferably both capable of communicating on, and are interconnected by, an insurer local area network 24. The provider interface computers and the information-exchange computer are preferably capable of communicating on, and are interconnected by, the Internet 26 or dial up access over a POTS (Plain Old Telephone Service) line. The insurer or third party claim processor and review agency computers may alternatively be connected to the information-exchange computer either by the Internet or dial up access.

The computers are integrated for the performance of three main functions: (1) enrollment of subscribers; (2) submission and processing of claims; and (3) preparation and processing of prior authorization requests. These functions are depicted in FIGS. 2, 3 and 4, respectively. In addition, the provider may use data screens available on the provider interface computers, such as shown in FIGS. 5-8, for confirmation of benefit plan and eligibility of subscribers.

As shown in FIG. 2, enrollment begins with a subscriber obtaining insurance coverage from an insurer and providing data to a health plan enrollment department. Subscriber insurance data is then entered into a Healthcare Information System (HIS) software application operable on the insurer's computer. The subscriber insurance data includes information on subscriber demographics or enrollment data, eligibility, selected benefit package and selected primary care provider. A typical data screen for demographics, used by the health plan enrollment department during data entry, includes fields for subscriber (or member) number, name, address, employer, dependents and other information, as shown in FIG. 5. A typical data screen for benefit package information is shown in FIG. 6. Eligibility information is entered on a data screen such as that shown in FIG. 7. A data screen, such as that shown in FIG. 8, provides for assignment of a primary care physician that the subscriber has selected from a list of credentialed doctors.

Subscriber insurance data for a group of subscribers is stored on the insurer computer in an insurer database. The insurer has multiple health care providers for the group of subscribers. A subgroup of subscribers is assigned to each one of the health care providers. The information-exchange system is designed to be adaptable to any insurer computer in the present or future marketplace. These insurer computers may be mainframe computers, or more typically a midrange computer such as IBM's AS/400. The insurer database is part of the HIS application, which is a large, complex software application accessible by many other departments of the insurer in addition to the enrollment department. The insurer database is typically in a predetermined format, such as DB2, VSAM, ISAM or Btrieve, which is proprietary and unique to each insurer. Nonetheless, the information-exchange system is adaptable to any insurer database by customizing a translator which provides an interface between the proprietary insurer database and the information-exchange computer's database.

LAN software is installed on the insurer computer to enable it to communicate over an insurer local area network as depicted in FIG. 1. The LAN software may be part of the HIS, provided separately or provided as part of the information-exchange system when not available otherwise. The local area network provides a conduit for the subscriber insurance data to be transmitted to the information-exchange

computer. The information-exchange computer includes LAN software making it capable of communicating on the local area network to receive the subscriber insurance data. Although the local area network is preferably a network such as an Ethernet or token ring network, as is typically used by the HIS, it will be understood that a simple serial channel connection or modem line could be used as well.

The information-exchange system includes software installed and operable on the information-exchange computer or web server. This software is referred to as a server module and includes a translator which makes database requests to the insurer database and imports the resulting data, automatically translating the data for storage in an exchange database located on the information-exchange computer. The translator is customized to accommodate the particular insurer database format in use.

The exchange database is preferably stored in a predetermined open database-compliant or ODB-compliant format different from the format of the insurer database. ODB-compliant databases include those developed using database standards or programs such as Access, SQL and others. Economy in programming costs is obtained by making the exchange database in a single configuration that can be made to be compatible with any insurer and any provider by appropriate translators for automatically reformatting the incoming data. The insurer database is typically neither an SQL database nor ODB-compliant.

The information-exchange computer is capable of communicating either through the Internet at a high bandwidth or through a bank of modems for dial up access to speed communications with a large number of health care providers. The subscriber insurance data is preferably broadcast out to the appropriate providers using push technology.

Each provider that accepts patients from the insurer is furnished with an interface computer, e.g., a PC, capable of sustaining an Internet Protocol (IP) address to permit communication through the Internet or capable of dial up access. The interface computer may alternatively be any hand-held device capable of a modem or satellite uplink connection to the Internet, i.e., any device capable of sustaining an IP address. The provider interface computer forms a part of the information-exchange system, referred to as a client module or the provider interface portion.

Push technology is used to transmit information between the information-exchange computer and the provider interface computer. Push technology is a method of communication employed by a server computer to communicate with a client computer. This technology may be conducted over an internally hardwired network (i.e., a Local Area Network with Category 5 wiring using a 10BaseT Ethernet scheme), across a dial up network via modem access (Wide Area Network) or through the Internet.

The push method begins with the installation of a client software application, which is used by the server to identify the client on the network. The client also uses this application as a subscribing device to order customized information. The user of the client application enters requests for specific classes of information and preferred frequency of updates.

After receiving this user specific information, the server fashions a response based upon inherent features of the server application and the user requests. The server then pushes the customized information across the network to the client, hence the name push technology.

Push technology ensures that the data on the provider interface computer is always kept up-to-date because the

data is pushed out to the provider interface computer and into a provider database located therein rather than requiring the provider to pull the data down from the information-exchange server. Push technology as implemented in the information-exchange system includes three components: channels, which are applications or information which are distributed across the Internet, dial up network, or LAN; an application running on the information-exchange computer which manages the distribution and maintenance of the channels; and an application on the provider interface computers which monitors, receives and manages the channels. In the information-exchange system, an application pushed as a channel is operable on the provider interface computers to make entries, modifications and deletions within the provider database using information which has also been distributed as a channel.

The push technology on the information-exchange computer is preferably a Castanet™ transmitter, produced by Marimba™. The provider interface computer includes a complementary tuner to receive the subscriber insurance data for storage in the provider database. Push technology is also available from PointCast™ and WebCast™. The push transmitter has a built-in capability to encrypt data and sends the encrypted subscriber insurance data, either over the Internet or through dial up access, to the subscriber's assigned Primary Care Provider (PCP) whose provider interface computer is tuned to receive that data. The transmitter also sends an application over the Internet or through dial up access, such as a Java applet, that is operable on the provider interface computer to decrypt and store the subscriber insurance data in the provider database. The tuner also has the capability to encrypt and push data to the transmitter. As seen in FIG. 1, a plurality of provider interface computers may be connected to the information-exchange computer over the Internet or through dial up access. These provider interface computers may also receive subscriber insurance data from, and communicate with, other information-exchange computers operated by other insurers whose coverage the providers are authorized to accept. Each provider interface computer stores the subscriber insurance data in its own provider database.

In addition to the new subscriber scenario, other situations will arise in which the data for the subgroup of insurance subscribers in each provider database should be updated. For instance, an existing subscriber may choose to change primary care providers in which case a deactivation message is broadcast to the old provider and subscriber insurance data is broadcast to the new provider. Also, when an insurer credentials new providers, the new provider is typically assigned a batch of previously unassigned subscribers. The subscriber insurance data for all of the subscribers is broadcast out to the newly-credentialed provider. Push technology is used in all of these situations to broadcast the subscriber insurance data to the providers. One major advantage of the invented system is that the provider is kept up-to-date on patient/subscriber status without any direct intervention on the part of the provider.

The provider may also have a pre-existing practice management system (PMS), which is an application that may be operable on a separate practice management computer, shown at 28 in FIG. 1, or, in some cases, on the provider interface computer. In a large office of providers, the practice management system computer may be an RS6000, while in a small office it may be a 286-based PC. With the PMS installed on a practice management computer, the provider interface portion automatically translates the enrollment demographics and benefit plan name and transmits it over a

provider local area network 30 to the practice management computer. Preferably, in a Unix-based PMS, such as are common, this transmission makes use of file transfer protocol, or ftp.

Thus, when the subscribers arrive at their chosen provider's office, the subscriber insurance data is already available and current at the office and does not need to be reentered or remotely checked via telephone. The provider may review the subscriber's data using appropriate software installed on the provider interface computer or using the PMS. In addition, if the subscriber discovers at the provider office that some subscriber demographics in the provider database are incorrect either because of a data entry error at the insurer or change to the subscriber's circumstances, changes to the database may be made to the provider database. The tuner in the client application will then push the changed information to the transmitter on the information-exchange computer for entry into the exchange database and ultimately the insurer database.

In the information-exchange system, the translator installed on the information-exchange computer makes it possible to have automatic transmission of subscriber insurance data between the insurer and provider even when the insurer database and the provider database are mutually incompatible. The insurer database may have any unique or proprietary format. The provider database is preferably ODB-compliant which is typically incompatible with proprietary formats. The various provider PMSs also typically use unique data formats, most of which are incompatible with one another. The provider interface portion on the provider interface computer allows communication between the information-exchange computer and any PMS despite the differing data formats because the provider interface portion can provide an appropriate customized translation for each PMS format.

The preparation, submission and processing of claims with the information-exchange system is depicted in FIG. 3. For providers with a legacy practice management system, entry of claims remains the same. In particular, the existing PMS is used to enter the International Classification of Diseases (ICD9) and Clinical Procedure Terminology (CPT) codes that represent the diagnoses and treatments of the patient-subscriber, respectively. The entry may be manual or an Electronic Medical record device may be used to automatically enter claims. Preferably, claims entered in this manner and assembled by the PMS are transmitted over the provider local area network as an ASCII flat file to the provider interface portion of the information-exchange system. Providers not using an existing PMS may enter claims information directly manually, on the provider interface computer using a claim data entry interface in the provider interface portion that replicates some features of a PMS or with an Electronic Medical record device. A data entry screen for claims is shown in FIG. 9. For claim entry either through the PMS or the provider interface portion, the provider interface computer receives the claims and stores the claims in the provider database.

In the preferred embodiment, the provider interface computer transmits the claims, either over the Internet in encrypted fashion or through dial up access, to the information-exchange computer. Preferably, the tuner in the client application encrypts and pushes the claims to the transmitter in the information-exchange computer. As seen in FIG. 3, multiple provider offices with PMS and provider interface computers are capable of transmitting to the information-exchange computers. Because each provider may have patients from several insurers, each of whom have

their own information-exchange computer, the provider interface computer must be able to transmit claims to multiple information-exchange computers.

The transmitted claim is stored in the exchange database and translated for transmission to the insurer or to a third party claim processor's or administrator's computer. Transmission to the insurer's or third party's computer is preferably conducted over the insurer local area network. However, the transmission, especially to the third party's computer, which in some cases may be located offsite, may be done either over the Internet or through dial up access. It will be understood that a third party's computer is typically provided with network communication capabilities and a third party database equivalent to the insurer database on the insurer's computer and that transmission to the third party database, over a local area network, the Internet or through dial up access, is similar to transmission to the insurer database over the insurer local area network.

The insurer or administrator computer receives the claim and stores it in the insurer database. Once the claims processing department receives the claim, the staff verifies the member's eligibility, confirms the benefit package, and, for specialist provider claims and other claims requiring prior authorization, accesses a prior authorization module of the HIS application. The ICD9 codes, CPT codes and the approval number in the approved prior authorization request must identically match those stipulated in the claim. If an identical match exists, or if the claim is covered by the benefit package without prior authorization, the staff member in the claims processing department approves the claim and initiates payment. The amount of payment is determined by the CPT codes and their associated payment scheduled contained in the provider's contract.

Initiation of payment procedures by the claims processing staff originates an electronic payment. This electronic payment transaction is communicated over the network connection to the information-exchange computer. The information-exchange computer first configures the electronic payment and the accompanying documentation. Then, the information-exchange computer transmits the electronic Explanation of Benefits (EOB) to the provider interface computer and transmits the electronic payment to the provider's financial account of choice.

The processing of prior authorization requests, as depicted in FIG. 3, begins with the entry of a prior authorization request using the provider interface portion on the provider interface computer. Typical data entry screens for the prior authorization request are shown in FIGS. 10-16. FIG. 3 shows the steps of the prior authorization data being stored in the provider database and then transmitted via push technology, either over the Internet or through dial up access, to the exchange database on the information-exchange computer.

The information-exchange system translates the prior authorization data into the insurer database format and transmits the data to the HIS over the insurer local area network. If a third party review agency located offsite handles the prior authorization requests, the data may be transmitted, over a local area network, the Internet or through dial up access, directly, or via the insurer computer, to a third party computer configured to receive the prior authorization requests and to process the prior authorization request based on the information transmitted.

The insurer or review agency processes the prior authorization request and makes a determination of approval or denial. Processed prior authorization requests are transmit-

ted over the insurer local area network, the Internet or through POTS lines to the information-exchange computer, passing through the translator which automatically translates the processed prior authorization for storage in the exchange database. The information-exchange system then transmits approved prior authorization requests to a specialist provider interface computer, configured similarly to a provider interface computer to receive processed prior authorizations and the provider interface computer. Denied prior authorizations are preferably transmitted to the provider interface computer only.

While the present invention has been shown and described with reference to the foregoing preferred embodiment, it will be apparent to those skilled in the art that other changes in form and detail may be made therein without departing from the spirit and scope of the invention as defined in the appended claims.

I claim:

1. A system for controlling the exchange of information between an insurer and multiple health care providers in a health care delivery system, where each health care provider is assigned a subgroup of subscribers from a group of subscribers within the insurer's health plan, the system comprising:

an insurer computer configured to maintain an insurer database of subscriber insurance data on the group of the insurer's subscribers, the database having a first predetermined format;

an information-exchange computer operatively connected to the insurer computer to receive at least some subscriber insurance data on the group of the insurer's subscribers therefrom, the information-exchange computer being configured to store that subscriber insurance data in an exchange database in a second predetermined format that is different from the first predetermined format; and

plural provider interface computers located at plural corresponding health care providers offices, each provider interface computer being operatively connected to the information-exchange computer to receive therefrom and store in a provider database subscriber insurance data for the subgroup of subscribers assigned to the provider, where changes in subscriber insurance data for each subgroup stored in the insurer computer are automatically transmitted to the information-exchange computer and then forwarded to the provider interface computer corresponding to the provider to whom the subgroup is assigned, to thereby automatically maintain the currency of the provider database as the subscriber insurance data changes.

2. The system of claim 1 wherein the subscriber insurance data are transmitted from the information-exchange computer to the first provider interface computer using push technology.

3. The system of claim 1 further comprising plural practice management system applications corresponding to the plural provider interface computers wherein the subscriber insurance data stored in each provider database are translated automatically and transmitted to each practice management system.

4. The system of claim 3 wherein at least one of the practice management system applications is operable on a practice management computer.

5. The system of claim 4 wherein the practice management computer communicates with the corresponding provider interface computer over a provider local area network.

6. The system of claim 3 wherein at least one of the practice management system applications is operable on one of the provider interface computers.

7. The system of claim 1 wherein the insurer database and at least one of the provider databases are mutually incompatible.

8. The system of claim 7 wherein the exchange database is ODB-compliant.

9. The system of claim 8 wherein the insurer database is not ODB-compliant.

10. The system of claim 7 wherein the exchange database is an SQL database.

11. The system of claim 10 wherein the insurer database is not an SQL database.

12. The system of claim 1 wherein at least two of the practice management systems have differing formats for the subscriber insurance data.

13. The system of claim 1 wherein at least one of the provider interface computers is configured to receive subscriber insurance data from a second information-exchange computer.

14. A system for exchanging information between an insurer providing insurance coverage to a subscriber for medical care at a health care provider, the subscriber being assigned to the health care provider and the data being exchanged over an insurer local area network and a network using an open communications protocol, the system comprising:

a first practice management system application configured to assemble claims;

a first provider computer capable of communicating on the open network, the first provider computer being configured to receive the claims from the first practice management system application, to store the claims in a first provider database and to transmit the claims over the open network;

an information-exchange computer capable of communicating on the insurer local area network and the open network, the information-exchange computer being configured to receive the claims from the first provider computer over the open network, to store the claims in an exchange database and to automatically translate and transmit the claims over the insurer local area network; and

an insurer computer capable of communicating on the insurer local area network, the insurer computer being configured to receive the claims from the information-exchange computer over the insurer local area network and to store the claims in an insurer database.

15. The system of claim 14 wherein the first practice management system application is operable on a practice management computer connected to the first provider computer by a provider local area network.

16. The system of claim 15 wherein the claims are transmitted from the first practice management computer to the first provider computer over the provider local area network in an ASCII flat file.

17. The system of claim 14 wherein the first practice management system application is operable on the first provider computer.

18. The system of claim 14 further comprising

a second practice management system application configured to assemble claims; and

a second provider computer capable of communicating on the open network, the second provider computer being configured to receive the claims from the second practice management system application, to store the claims in a second provider database and to transmit the claims over the open network,

13

wherein the information-exchange computer is configured to receive the claims from the second provider computer over the open network, to store the claims in an information-exchange database and to automatically translate and transmit the claims over the insurer local area network.

19. The system of claim 14 wherein the first provider database and the insurer database are mutually incompatible.

20. The system of claim 14 wherein the provider interface computer transmits the claims over the open network via push technology.

21. A system for exchanging information between an insurer providing insurance coverage to a subscriber for medical care at a health care provider, the subscriber being assigned to the health care provider and the data being exchanged over an insurer local area network and a network using an open communications protocol, the system comprising:

a first provider computer capable of communicating on the open network, the first provider computer being configured to allow a user to prepare a prior authorization request;

an information-exchange computer capable of communicating on the insurer local area network and the open network, the information-exchange computer being configured to receive the prior authorization request from the first provider computer over the open network and to store the prior authorization request in the information-exchange computer in an exchange database; and

14

an insurer computer capable of communicating on the insurer local area network, the insurer computer being configured to receive the prior authorization from the information-exchange computer and to store the prior authorization in an insurer database,

wherein the prior authorizations stored in the exchange database are translated automatically to the insurer database.

22. The system of claim 21 wherein the insurer computer is further configured to transmit via push technology a processed prior authorization to the information-exchange computer.

23. The system of claim 22 wherein the information-exchange computer transmits the processed prior authorization to the first provider computer and wherein the first provider computer is further configured to receive the processed prior authorization and to store the response in the provider database.

24. The system of claim 21 further comprising a specialist computer configured to receive the processed prior authorization and wherein the information-exchange computer transmits the processed prior authorization to the specialist computer.

* * * * *